SAIC FREDERICK **SOLICITATION, OFFER AND AWARD**	Maryland Sales and Use Tax Direct Pay Permit No. 3	Page 1 of 75 Pages

2. Subcontract No.	**3. Solicitation No.**	4.X Sealed Bid (IFB) Solicitation ☐ Negotiated (RFP) Solicitation	**5. Date Issued**	6. Requisition/ Purchase Order:
**********	SO4 -145		10/08/04	**PR: FF0312**

7. Issued By/Address Offer To:	8. Delivery Date: See Section F
Eugene B. Anderson, Supervisor, Subcontracts, , SAIC Frederick, Inc. NCI-Frederick Cancer Research & Development Center P.O. Box B, Miller Drive, Fort Detrick Frederick, Maryland 21702-1201 PH: 301-228-4008 FX: 301-228-4037	8A. Place of Delivery: See Section F 8B. XX FOB Destination ☐ Other

Note: In sealed bid solicitations *"offer"* and *"offeror"* mean *"bid"* and *"bidder"*.

SOLICITATION

9. To be timely, sealed offers, an original and 2 copies must be received at the room specified in Item 7 by 2:00p.m. EDT
10. Envelopes shall be marked to show solicitation number, and time and date of opening. _____ (hour)_____(date)

11. OFFER/SUBCONTRACT CONSISTS OF:

Part I – The Schedule
A. Solicitation/Contract Form
B. Supplies or Services and Prices/Costs
C. Description/Specs./Statement of Work
D. Packaging and Marking
E. Inspection and Acceptance
F. Deliveries or Performance
G. Contract Administration Data
H. Special Contract Requirements

Part II – Contract Clauses
I. Contract Clauses
Part III – List of Documents, Exhibits and Other Attachments
J. List of Attachments
Part IV – Representations and Instructions
K. Representations, Certifications and Other Statements of Offerors
L. Instructions, Conditions, and Notices to Offerors
M. Evaluation Factors for Award

SCHEDULE

ITEM NO.	SUPPLIES/SERVICES	QTY.	UNIT	UNIT PRICE	AMOUNT
	SEE STATEMENT OF WORK IN SECTION C.	-----	-------	----------	

12. In compliance with the above, if this offer is accepted within __ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item in accordance with the terms of the offer. Note: Sealed bids providing less than __ calendar days for acceptance will be considered non-responsive and rejected.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section D, Clause No. 52.232-8)*	10 CALENDAR DAYS %	20 CALENDAR DAYS %	30 CALENDAR DAYS %	CALENDAR DAYS %

14. ACKNOWLEDGMENT OF AMENDMENTS *The offeror acknowledges receipt of amendments to the solicitation for offerors and related documents numbered and dated:*	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. Name and Address of Offeror: **DUNS NO.:** **Taxpayer/Exempt ID:**	16. **Name and Title of Person Authorized to Sign Offer** ***(Type or Print)*** **Name/Title:** _____ **PH:** _____ **FX:** _____

15B. Telephone No: (*Include Area Code*):	**15C.** ☐ Check if remittance address is different from above. Enter such address in schedule.	**17. Signature**	**18. Offer Date**

AWARD *(On this form or by other written notice)*

19. Accepted As To Items Numbered:	20. Amount:	21. Accounting Data:

22. Submit Invoices following instructions of Article G.3 of Solicitation *(3 copies unless other specified)*

23. Name/Title of Person Authorized to Sign for SAIC-Frederick, Inc.: **Annette Bishop, MBA, CFCM** **Manager, Research Contracts**	**24. SAIC Authorized Signature:**	**25. Award Date**

PART I—THE SCHEDULE

SECTION B—SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

Independently, and not as an agent of the Government, the Subcontractor shall furnish all necessary services, qualified personnel, materials, equipment, and facilities not other wise provided by the Government and/or SAIC-Frederick, Inc. under the terms of this Subcontract, as needed to perform the Statement of Work (SOW) herein. Subcontractor shall perform the full Scope of Work, as defined in Section C, as needed, to provide monitoring of two clinical research protocols, monitoring of laboratory facilities and procedures for obtaining, testing and storing clinical research specimens, when requested, site initiation and close-out visits, training of site personnel. See Section C, Scope of Work, for detailed tasks and deliverables.

ARTICLE B.2. TYPE OF CONTRACT

A. SAIC-Frederick, Inc. contemplates award of a Cost Plus Fixed Fee Subcontract (CPFF) resulting from this solicitation, as defined in FAR Part 16.306. A cost-reimbursement Subcontract provides for payment of allowable incurred costs, to the extent prescribed in the Subcontract. The Subcontractor may not exceed the established estimated cost without the written authorization of the Contracting Officer.

B. To allow the greatest level of competition, SAIC-Frederick will accept and evaluate Time and Material (T&M) responses to this solicitation. Time and Material responses should be fully loaded inclusive of profit. Sufficient basis of estimate will be required to evaluate a T&M pricing to CPFF offers. Should a T&M Subcontract, as defined in FAR 16.601, result from this solicitation clauses applicable to CPFF Agreements will be deleted and clauses applicable to T&M Agreements will be added. This will include FAR references in Part II Section I.

ARTICLE B.3. PRICES/COSTS

A. This Subcontract is for a one (1) year period from the date of full execution by the Contracting Officer. This contract as stated at Section F. Deliveries or Performance provides for two one (1) year options.

B. Proposed costs shall be submitted in the format provided as **Attachment 1** for each of the years as described in Section F.1 and Section L.6.

C. The total estimated cost of this Cost-Reimbursement Subcontract is $_____. (To be provided by Offeror.)

D. Total funds in the amount of $ _____ have been allotted for obligation and are available for payment of allowable costs to be incurred from the effective date of this Subcontract through _____, and is not to be exceeded without prior Contracting Officer approval in the form of a modification to this Subcontract. (To be provided by SAIC-Frederick at the time of award of this Subcontract.)

E. The Subcontractor shall notify SAIC-Frederick, Inc. in writing whenever it has reason to believe that the costs it expects to incur under this Subcontract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the total amount so far allotted to the Subcontract by SAIC-Frederick, Inc.

F. It will be noted that both the Limitation of Cost and the Limitation of Funds clauses (Part II, Contract Clauses, Section II, Article I.1.A.) are incorporated into this Subcontract. This has been done with the express understanding that in those instances where the Subcontract is in an incrementally funded status, the Limitation of Funds clause shall be applicable; and when full contract funding has been effected, the Limitation of Cost clause shall prevail. At no time shall the two clauses be concurrently operative.

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

A. Items Unallowable Unless Otherwise Provided

Notwithstanding the clause, ALLOWABLE COST AND PAYMENT, incorporated in this Subcontract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

(1) Acquisition, by purchase or lease, of any interest in real property;
(2) Special re-arrangement or alteration of facilities;
(3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property, which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
(4) Travel to attend general scientific meetings, whether at domestic or foreign locations;
(5) Consultant expenses; and
(6) Subcontracts

B. Travel Costs:

Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this Subcontract shall not exceed $ 0.00 without prior written approval of the Contracting Officer. Travel will be reimbursed in accordance with SAIC-Frederick, Inc.'s travel guidelines and the Joint Travel Regulation (http://www.state.gov/m/a/als/prdm/).

ARTICLE B.5. INDIRECT COST RATES

In accordance with the FAR Clause No. 52.216-7(d)(2), Allowable Cost and Payment, which is incorporated into this Subcontract, indirect cost rates reimbursable hereunder shall be consistent with those established by the Cognizant Federal Audit Agency for your organization, as may be amended. Final approval will be determined by the Contracting Officer.

ARTICLE B.6. ADVANCE UNDERSTANDINGS

A. Items to be Furnished to the Contractor: ***To be determined***

B. Pre-award Expenses: No pre-award expenditures will be authorized.

C. Intellectual Property: No intellectual property transfer anticipated for this contract.

ARTICLE B.7. GOVERNMENT PROPERTY

The parties agree that no non-expendable property or equipment will be acquired or furnished under this Subcontract, unless prior written authorization is obtained from the Contracting Officer.

SECTION C—DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK

1. INTRODUCTION AND BACKGROUND INFORMATION

1.1 Overview

This Regulatory Oversight and Clinical Site Monitoring Project contract will provide services performed by a selected Clinical Research Organization (CRO). The services will include, but are not limited to:

(1) Monitoring of three clinical research protocols:
- a) Pimonidazole for Tuberculosis (TB): A potential US-FDA/Korean IND study with projected enrollment of 10 subjects over a one-year period.
- b) Metronidazole for TB: A non-IND study with projected enrollment of 30 subjects over a one-year period.
- c) A TB Natural History Study with projected enrollment of 1840 subjects over a four year period.

(2) All three studies are to be conducted at one designated site in the Republic of Korea:
- a) National Masan Tuberculosis Hospital (NMTH), Masan, Republic of Korea

(3) Recruitment will take place at multiple sites.

(4) Monitoring of laboratory facilities and procedures for obtaining, testing and storing clinical research specimens, when requested as a special assignment. There are three clinical laboratories:
- a) Tuberculosis Clinical Research Center, NMTH
- b) Yonsei University, Masan, Kyungnam
- c) Hospital in Masan (NMTH)

(5) Site initiation and Site Close-out visits, as needed.

(6) Assisting with necessary training of site personnel on International Conference on Harmonization (ICH)/Good Clinical Practice (GCP); the US Food and Drug Administration (FDA); the Office for Human Research Protection (OHRP), and the policies and procedures to conduct clinical research established by the Korean Ministry of Health, when applicable.

(7) Timely maintenance of a database of monitoring reports, monitoring findings and problem resolution and training activities.

(8) As needed, provide regulatory guidance and oversight for the clinical protocols. When requested, be responsible for the preparation, submittal, maintenance of the IND (or equivalent) and for submission of additional documents to the Korean FDA, as required by the Korean rules and regulations.

(9) Review and forward the Serious Adverse Experience (SAE) form completed by the Clinical Trials Site Investigator to RCHSPP/SAIC-Frederick, Inc. Clinical Safety Group within the designated timeframe.

(10) Communication and coordination with NIH designees or Investigators and the Regulatory Compliance and Human Subjects Protection Program (RCHSPP)/SAIC-Frederick, Inc. Regulatory Affairs Department and Clinical Trials Management Team to enhance the quality of the clinical research. (Note: RCHSPP/SAIC-Frederick, Inc. supports the NIH/NIAID Intramural Research Program, Regulatory Compliance and Human Subjects Protection Branch (RCHSPB. RCHSPB is the sponsor of the studies and may potentially hold a US FDA IND for the Pimonidazole study).

(11) Capacity to rapidly intensify the regulatory oversight and/or monitoring effort in the event additional protocols are initiated.

[Specific responsibilities of the CRO are described below in Section 2.0 and 3.0, Work Statement]
NOTE: Definition of "Monitoring:" The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s). (ICH)
Definition of "Monitoring Visit:" A visit to a study site to review the progress of a clinical study and to ensure protocol adherence, accuracy of data, safety of subjects, and compliance with regulatory requirements and good clinical practice guidelines.

Definition of "Serious Adverse Drug Experience/Serious Adverse Event (SAE):" Any adverse experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject any may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization or the development of drug dependency or drug abuse. (21 CFR 312.32a)

1.2 General Notes: Special Instructions to the Offeror:

(1) It is important that the contractor assign CRAs to the studies who are **fluent in Korean and English, both orally and in written communications.**
(2) Be familiar with Korean, ICH, and US regulations.
(3) Have experience/knowledge of tuberculosis (TB) disease process and treatment.
(4) In addition, it would be preferred that the same CRAs be assigned to these studies for the duration of the studies.
(5) Describe in detail the responsibilities and time commitment for all personnel who will be assigned to the contract, and an administrative framework showing clear lines of authority.
(6) Provide documentation on the decision-making authority of key personnel, the extent to which outside consultants will be used as well as assurance of their availability, and the percentage of time each staff member (including proposed subcontractors and consultants) will contribute to the project, if any.
(7) Provide an organizational chart of all personnel.
(8) Describe how monitors will be assigned to sites and whether they will be centrally, regionally, or locally based.
(9) Describe the educational and work experience of the monitors in the areas assigned.
(10) Describe **plans for training monitors and site personnel** to conduct research according to specified procedures, if required by the SAIC Clinical Trials Manager.
(11) Describe **the training curriculum** for site personnel with various levels of preparation and experience in clinical research.
(12) Provide a **detailed work plan** showing proposed time schedules adequate for achieving contract objectives and maintaining quality control over the implementation and operation of the project.
(13) All reports to RCHSPP/SAIC-Frederick, Inc. and to RCHSPB are to be in English.
(14) ***The Subcontractor is directed to the full text of any and all applicable federal and international regulations cited herein, including but not limited to:***
    a. United States Food and Drug Administration http://www.fda.gov/oc/gcp/default.htm
    b. Health and Human Services Regulations for Federally Funded Research http://www.hhs.gov/policies/index.shtml#laws
    c. HHSSAR 352-223-70- Safety and Health http://www.hhs.gov/ogam/oam/procurement/hhsar.html
    d. Declaration of Helsinki

http://www.wma.net/e/policy/be.htm

e. International Conference on Humanization http://www.ich.org
f. Korean FDA http://kfda.go.kr/
g. United States Code of Federal Regulations http://www.gpoaccess.gov/ecfr
    a. 21 CRF 11, Electronic Records, Electronic Signatures
    b. 21 CFR 50, Human Subjects Protection (Informed Consent)
    c. 21 CFR 50, Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products
    d. 21 CFR 54, Financial Disclosure by Clinical Investigators
    e. 21 CFR 56, Institutional Review Boards
    f. 21 CFR 312, Investigational New Drug Application
    g. 45 CFR Part 46, Protection for Human Subjects

Notice the following project milestones mentioned in Part 2.0, Work Statement:

DEADLINE	**DELIVERABLE**
Week 2-4	SOP for monitoring tasks (2.2.3.2) (CRFs and Protocol Specifics)
Month 1-2	SOP for training CRAs/monitors (2.2.1.2)
Month 1-2	SOP for training sites (2.3.1.1)
Month 1-2	Database of monitoring results established (2.3.8.1)
Month 2	All monitors required for initial group of trials (2.2.1.1)

In addition, the contractor will be expected to begin site- monitoring visits within one to two months of contract award.

NOTE #1 TO OFFEROR: PRE-AWARD:

(1) Provide resumes, endorsements, and explanations of previous efforts, which reflect length and variety of experience in similar tasks;
(2) Clearly demonstrate relevant training, expertise and specific accomplishments.
(3) Include examples of completed site monitoring visit reports.
(4) Document Korean presence and experience.

2. WORK STATEMENT

Independently and not as an agent of the Sponsor, the NIH/NIAID/Regulatory Compliance and Human Subjects Protection Branch (RCHSPB), the contractor shall furnish all necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by RCHSPP/SAIC-Frederick, Inc. as needed to perform the tasks described in Parts 2.1 through 4.0 of this Work Statement.

2.1 Study Set-Up Activities

2.1.1 Case Report Forms and Patient Diaries:

2.1.1.1 The CRO will be expected or asked to review the final draft of the case report forms (CRF's) and patient diaries if needed, and to translate applicable documents into Korean language. Final documents will require a back translation.

2.1.2 Informed Consents

2.1.2.1.1 The CRO may be expected to assist with the translation of the informed consents into Korean. The CRO must certify that all translations are accurate, legally reliable, and compliant with all

government regulations as applicable to this scope of work.

2.1.2.1.2 The CRO may be expected to work with the site to negotiate and implement modifications to the informed consents as needed throughout the study in collaboration with RCHSPP/SAIC-Frederick, Inc.

2.2 Pre-Trial Activities

2.2.1 Recruit And Train Site Monitors

2.2.1.1 Within one month following contract award, the contractor shall recruit and train at least all monitoring staff needed for the initial trial being conducted or planned. All monitors shall:

a) Have a Bachelor's degree or equivalent in nursing, pharmacy, biology, or other biomedical sciences;
b) Be fluent in Korean and English (both orally and written);
c) Have experience in clinical research, and have experience in clinical trials site monitoring, working on TB studies, working with community and hospital clinic staffs, and teaching clinical staff;
d) Be knowledgeable of the regulatory requirements in Korea and with the health care systems and all applicable clinical research regulations; and;
e) Be knowledgeable of the ICH/GCP and US FDA regulatory requirements.

2.2.1.2 Within one to two months following contract award, the contractor shall develop and submit to the Clinical Trials Manager (CTM) or Lead CRA at RCHSPP/SAIC-Frederick, Inc. for approval the contractor's SOP for initial and ongoing training of monitors. The plan shall address the frequency of training, the mechanisms to be used (e.g., lectures, regional training, written guidelines and on-the-job training) and the curriculum.

2.2.2 Critical Study Documents

2.2.2.1 The CRO will assist in collection of the critical study documents. At a minimum these documents include: (CV's, IRB/Ethics Committee approval letters and approved protocol and informed consent form(s), laboratory normal range values, laboratory certifications, and authorized representative signature sheets, and others as may be requested by RCHSPP/SAIC-Frederick, Inc.).

2.2.3 Project Planning

2.2.3.1.1 The CRO will be responsible for the establishment of a project team (see section 1.2, General Notes and section 2.2.1, Recruit and Train Site Monitors).

2.2.3.1.2 Within two to four weeks following contract award, the contractor shall develop and submit for approval to the CTM or Lead CRA at RCHSPP/SAIC-Frederick, Inc. a written Standard Operating Procedure (SOP) for accomplishing the monitoring tasks described in this Work Statement. The contractor shall periodically revise this SOP at the request of the CTM or Lead CRA at RCHSPP/SAIC-Frederick, Inc. to ensure that it accurately reflects the monitoring work the contractor is required to perform.

2.2.3.2 The CRO will be required to submit their appropriate company SOP's for review and comment by RCHSPP/SAIC-Frederick, Inc. If these SOP's are determined to be adequate, these SOPs will be used or RCHSPP/SAIC-Frederick, Inc. may request that study specific SOP's be written by the CRO.

2.2.3.3 The CRO will be responsible for providing the CTM or Lead CRA at RCHSPP/SAIC-Frederick, Inc. with all information needed to update Performance Metrics.

2.2.3.4 The CRO will be responsible for the development of the appropriate Monitoring Template or Tracking Documents.

2.2.3.6 The CRO will need to review RCHSPP/SAIC-Frederick, Inc. SOP's for the flow of CRF collection.

2.3 Study Conduct/During Active Study

2.3.1 Train Site Staff in Policy, Procedures, and Good Clinical Practice

2.3.1.1 Within one to two months following contract award, the contractor shall develop and submit to the CTM/Lead CRA at RCHSPP/SAIC-Frederick, Inc. for approval a written SOP for accomplishing the training tasks described in this Work Statement. The contractor shall periodically revise this SOP at the request of the CTM/Lead CRA at RCHSPP/SAIC-Frederick, Inc. to ensure that it accurately reflects the training work the contractor is to perform.

2.3.1.2 The contractor's CRA's shall conduct the training of both new and experienced clinical site personnel using mechanisms such as presentations at regular meetings of the research groups, written training guides, and conference calls, as well as training during site visits. The plans for such training will need to be reviewed in advance by CTM/Lead CRA.

2.3.1.3 The CRO will assist RCHSPP/SAIC-Frederick with site training to include:

a) Training in local and applicable Federal regulations and Good Clinical Practice guidelines for clinical research;
b) Training in the policies and procedures of the project,
c) Information and assistance to the site with respect to the responsibilities of site study staff, RCHSPP/SAIC-Frederick, and the identified laboratory as needed.

2.3.2 Site Initiation Visits

2.3.2.1 The CRO may be responsible for conducting up to three Site Initiation Visits with RCHSPB and RCHSPP/SAIC-Frederick Inc.

2.3.2.2 Prior to implementation of a clinical study at a new site, the CRO monitors and RCHSPP/SAIC-Frederick, Inc. shall conduct a site visit to include:

a) An assessment of the adequacy of the site facilities, e.g., the pharmacy, laboratories, specimen storage equipment, clinical unit, and secure storage area.
b) A thorough review of the following Federal regulations (for IND study) with the site personnel:
   - 45 CFR 46, regulations for the protection of human subjects
   - 21 CFR Parts 50, 56, and 312
c) A thorough review of the ICH/GCP regulations and applicable Korean regulations.
d) An orientation of the personnel at the drug management area and staff responsible for drug dispensing, with special regard to drug accountability record procedures, location of drug ordering forms, drug dispensing information, and contact information for further training by telephone, as needed.

2.3.2.3 If the CRO participated in the site initiation, the CRO may be responsible for collaborating and

assisting with writing and submitting a Site Initiation Report to RCHSPP/SAIC-Frederick, Inc. 15 to 20 days following the date of the visit (to be submitted to RCHSPP for review and a follow-up letter to the investigator prior to finalization). All reports submitted to RCHSPP/SAIC-Frederick, Inc. should be in English.

2.3.3 Monitor Clinical Sites, Pharmacies, and Laboratories

2.3.3.1 The CRO will be responsible for preparing the monitoring visit schedule.

2.3.3.2 The contractor's monitors shall visit sites conducting active protocols as follows:

1) Natural History Study (TB)
   a) Monitor sites three times each study year (3visits/year). This does not include study initiation and closeout visits.
   b) The first monitoring visit should occur 6 weeks after the first 10-15 eligible subjects have been enrolled on study.
   c) The monitor will verify a minimum of 10%, or percentage specified by the CTM lead, of source documentation of all subjects enrolled.
   d) Conduct extra visits as directed by the Project Leader (RCHSPP), (e.g., to sites experiencing significant problems conducting research, carrying an unusually high subject load, or performing complex or high-priority protocols).

2) Pimonidazole Study
   a) Monitor site at least 3x during the study period. This does not include study initiation and closeout visits.
   b) The first monitoring visit should occur 6 weeks after the first 3 eligible subjects have been enrolled on study.
   c) The monitor will verify a minimum of 10% or percentage specified by the CTM. Consent form verification to be determined on source documentation of all subjects enrolled.
   d) Conduct extra visits as directed by the Project Leader (RCHSPB), (e.g., to sites experiencing significant problems conducting research, carrying an unusually high subject load, or performing complex or high-priority protocols).

3) Metronidazole Study
   a) Monitor site two times (2x) during the study period. This does not include study initiation and closeout visits.
   b) The first monitoring visit should occur 6 weeks after the first 10 eligible subjects have been enrolled on study.
   c) The monitor will verify 100% of source documentation of all subjects enrolled.
   d) Conduct extra visits as directed by the Project Leader (RCHSPB), (e.g., to sites experiencing significant problems conducting research, carrying an unusually high subject load, or performing complex or high-priority protocols).

NOTE #2 TO OFFEROR: *Flexibility will be required of the contractor with respect to the schedule of site visits. If the site has enrolled a greater number of subjects, it may be logical to visit the site more often. For planning purposes, the offeror should assume that a monitor would spend 2-3 working days visiting a site, depending on monitoring workload factors such as number of subjects enrolled. Less frequent monitoring may be appropriate with fewer subjects enrolled or depending upon the nature of*

trials being conducted. The offeror should use the information in Exhibit 1 in developing a budget for this project.

2.3.3.3 Site visits shall routinely include the following tasks:

a) Chart reviews of the following:
- Verify that all reportable data/source documentation have been accurately captured on the CRFs as specified in section 2.3.3.2.
- Verify and follow up on 100% of the serious adverse events (SAEs).
- Determine that adequate source documentation is maintained.

b) Special protocol assignments: Review specified subject records to verify endpoints, adverse events or other specific data items, as requested by the assignment.

c) Assess the site's compliance with the requirements of the protocols being conducted and maintenance of clinical records including:
- Adherence to inclusion and exclusion criteria;
- Reporting of serious adverse experiences;
- Reporting of protocol violations;
- Registry of protocol exemptions/exceptions approved by the protocol team;
- Documentation of objective findings such as clinical endpoints and adverse reactions; and
- The adequacy of source documents, the recording of data onto CRFs, and its accurate entry into the central computer database.

d) Assess the site's compliance with the policies and procedures of NIAID, and Federal, and local regulations.

e) Assess the various components of the implementation of the clinical studies including:

- The procedures for requesting and obtaining biological samples;
- The procedures for requesting and obtaining laboratory and diagnostic reports and other clinical records;
- The site personnel's knowledge of specific approved protocols being conducted at the site; and
- The site personnel's knowledge of pharmacy procedures.

f) Follow up to verify correct handling of past site visit issues or findings.

g) The monitor should write and submit a Site Monitoring Visit Report to RCHSPP/SAIC-Frederick, Inc. for final approval within 15 working days following the monitoring visit. Once the Site Monitoring Visit Report has been approved, the CRO will forward the final report to RCHSPP/SAIC-Frederick, Inc. for filing in the master file. All reports submitted to RCHSPP/SAIC-Frederick, Inc. should be in English.

h) The monitor should write and send a Monitoring Follow Up letter to the site within 15 working days following the monitoring visit. The Follow Up letter must be reviewed and approved by RCHSPP/SAIC-Frederick prior to forwarding the letter to the site. The monitor

will forward a copy of the approved, signed follow-up letter to the sponsor for filing in the master file. All reports submitted to RCHSPP/SAIC-Frederick, Inc. should be in English.

2.3.3.4 The monitors shall be responsible for these additional tasks that shall be incorporated into regularly scheduled site visits at the intervals specified at sites involved in active protocols:

a) Site operations assessment: On an annual basis, as needed, describe the various components of the operation and management of each clinical site including:

- the site personnel and their roles, including staff responsible for day-to-day management of the site, outreach/recruitment, internal quality management, and maintenance of site regulatory files;
- communication channels among site staff;
- adequacy of the facilities and study equipment;
- availability of a secured area for storing confidential information (e.g., signed informed consents, research records); and compliance with specified procedures to protect confidentiality; and
- documentation of the site's implementation of periodic internal quality management activity.

b) Specific-protocol oriented investigational drug audit: On each site visit, perform an audit of the drug management area for the active protocols including, but not limited to, evaluation of:

- the drug management area procedures to ensure that the treatment regimens are being dispensed in accordance with the protocol;
- subject records, treatment assignment lists and accountability documents, to ensure that their confidentiality is maintained; and
- the proper management of the study to ensure that procedures are being followed to prevent diversion of treatment drugs. This will include performing inventories of investigational agents physically present and reconciliation with accountability records.

***NOTE #3 TO OFFEROR**: The drug management area may need to be visited more frequently than noted above if problems are detected.*

c) Essential File audits: On each site visit, perform an audit to ensure that the site's regulatory-related procedures and files are in order. The site should have on file the latest protocols and consents along with IRB-approvals, current laboratory certifications, current investigator's brochures, documentation of annual IRB renewals, and all safety reports issued.

***NOTE #4 TO OFFEROR**: Registering the site to participate in a protocol is the responsibility of RCHSPP/SAIC-Frederick, Inc. The RCHSPP/SAIC-Frederick, Inc. receives from the site a "site registration package" and, if satisfactory, approves the site for participation in the protocol. The site monitors need to ensure that the site has copies of these documents on file.*

2.3.3.5 The contractor's monitors shall be responsible for performing these special duties on an as-needed basis:

a) Site closeout visits: If a site discontinues participation in the study, ascertain that it has properly closed out all studies and has followed proper procedures for the storage of records

and the disposition of remaining supplies of study drug.

b) If applicable to the protocol, Investigational drug management area operations assessment: The investigational drug management area operations assessment will be performed at the time of the site initiation visits or at the first regularly scheduled semi-annual drug management visit that occurs after there is a change in pharmacy personnel or the pharmacy changes location. The investigational pharmacy operations assessment will be in addition to the specific-protocol oriented investigational drug audit performed at that visit.

On an as-needed basis, whenever there is a site initiation visit, or there has been a change of the Responsible Drug Management Personnel of Record or change in drug management area has changed location, perform a full audit evaluating:

- the organization and utilization of the drug management area and staff including, but not limited to, the Responsible Drug Management Personnel of Record and back-up personnel;
- adequacy of the facilities and equipment;
- communication between clinical staff and drug management area staff including mechanisms for receiving protocol update information from the clinical staff, adherence to written policies for handling investigational drugs, frequency of internal audits for reconciliation of accountability records, and disposition of investigational agents from closed protocols.

NOTE #5 TO OFFEROR: *(Whenever there has been a change of the responsible drug management or personnel of records, in most cases the previous responsible personnel of record will provide orientation to the new personnel. The monitor will ascertain if this orientation has been done and if not, will orient the new personnel to the guidelines manual with special regard to accountability record procedures, location of investigational agent ordering forms, and pharmacy contact information for further pharmacy training by telephone, as needed.)*

c) Laboratory audits: As a special assignment, confirm adequate staff training and procedures regarding the collection, labeling, routing, and storage of laboratory specimens used as study endpoints. Determine the location of 5% of the samples of stored specimens or as agreed upon with the Project Team Leader to ensure that central database records are consistent with site specimen storage and clinical and laboratory site records. Ensure that the storage facilities are consistent with current guidelines with respect to temperature, specimen labeling, and specimen storage system, and that appropriate backup equipment is available.

2.3.4 Medical Monitoring

NOTE #6 TO OFFEROR: *(According to the United States (US) FDA Code of Federal Regulations (CFR) (312.32), the US Sponsor must notify the US FDA of any adverse experience associated with the use of the drug that is both serious and unexpected in human clinical trials. To fulfill this obligation, the Site Investigator is responsible for completing the Serious Adverse Experience (SAE) Form and forwarding to the CRO. The CRO is responsible for reviewing and forwarding the SAE Form to RCHSPP/SAIC-Frederick, Inc. Clinical Safety Group within the designated timeframe.)*

2.3.4.1 The CRO will be responsible for providing training to the site personnel on identifying Serious Adverse Experiences (SAE) according to the definitions outlined in the protocol.

2.3.4.2 The CRO will instruct site personnel in regards to completing the SAE Form. The SAE Form must be completed in English. If it is not, the CRO will be responsible for providing an English translation of the information submitted by the site.

2.3.4.3 The CRO will review the SAE Form for completeness prior to forwarding to RCHSPP/SAIC-Frederick, Inc. Clinical Safety Group. If the form is not complete, the CRO will follow-up with the site to obtain the required information.

2.3.4.4 If the RCHSPP/SAIC-Frederick, Inc. Clinical Safety Group requires additional information, the Clinical Safety Group will provide a list of questions to the CRO for follow-up with the site. It is the responsibility of the CRO to contact the site to obtain the additional information and provide it to the Clinical Safety Group within the designated timeframe.

2.3.4.5 It is the responsibility of the CRO to report all safety issues/information to the Korean FDA according to the Korean rules and regulations. The CRO will forward all safety information reported to the Korean FDA to the RCHSPP/SAIC-Frederick, Inc. Clinical Safety Group.

2.3.5 Project Management

2.3.5.1 The CRO will be responsible for maintaining all monitoring study tracking documents and will provide this information to the CTM or Lead CRA when requested.

2.3.5.2 The CRO will assist RCHSPP/SAIC-Frederick, Inc. in coordinating and participating in teleconferences. These teleconferences will initially occur weekly; after an initial period the teleconferences will occur every 3-4 weeks.

- The CRO will produce the agenda 48 hours prior to the teleconference.
- The CRO will produce the meeting minutes within 5 days following the teleconference.

2.3.5.3 The CRO will organize and conduct conference calls with the CRA(s) every month and RCHSPP/SAIC-Frederick, Inc.

2.3.5.4 The CRO will be responsible for coordinating the monitoring study timelines and providing updates to RCHSPP/SAIC-Frederick, Inc. Subcontractor agrees to produce monthly distribution of study monitoring data, previous to proposed teleconference calls.

2.3.5.5 The CRO will be responsible for notifying the CTM/Lead CRA of any major changes to their team structure and the monitoring project timeline.

2.3.6 Clinical Supplies

2.3.6.1 RCHSPP/SAIC-Frederick, Inc. will inform the CRO of the release of study drug to the site in order to verify drug accountability during routine monitoring visits.

2.3.7 Data Management

2.3.7.1 The CRO will assist with the transfer of the study data (via CRF) to RCHSPP/SAIC-Frederick, Inc

2.3.7.2 The CRO will assist RCHSPP/SAIC-Frederick, Inc. with the resolution of data discrepancies.

2.3.8 Provide Reports on Monitoring Findings and Training Activities

NOTE #7 TO OFFEROR: *All reports submitted to RCHSPP/SAIC-Frederick, Inc. and to RCHSPB must be in English.*

2.3.8.1 Within one to two months following contract award, the contractor shall have a fully functioning database of the results of site monitoring established and training, written in widely used, commercially available software, with the following capabilities:

a) Data entry and validation;
b) Documentation of data corrections;
c) Routine maintenance and backup; and
d) Data reporting and exporting if requested.

2.3.8.2 The contractor shall provide for the entry of data from the site monitors' worksheets listing subject records reviewed, dates through which the reviews were performed, number of each type of error detected, and resolutions to such errors.

2.3.8.3 The contractor shall generate reports as requested by the CTM/Lead CRA summarizing information in the monitoring database.

2.3.8.4 Within 20 days following completion of each site visit, the site monitor shall prepare a report that delineates the findings from the site visit. The site visit report shall include:

a) The name and address of the site visited and the dates of the visit;
b) A summary of the results of each monitoring and verification task performed;
c) A separate detailed listing by protocol and subject identification number of all deficiencies as revealed by the site monitoring visit;
d) When appropriate, recommendations for corrective actions to be taken to resolve any problems and deficiencies noted;
e) A description and assessment of any problems identified from previous visits which have not been corrected, the reasons why such problems have not been corrected, and recommendations for corrective actions when appropriate;
f) A summary of the monitor's debriefing of the site staff, including the names and titles of the staff with whom all problems and deficiencies have been discussed, a description of the site's plans for corrective action, and the site personnel responsible for implementing corrective action;
g) A brief description of improvements noted in site performance; and
h) When appropriate, a pharmacy audit report, a regulatory audit report, a laboratory audit report, a protocol training report, a site initiation report, or a site closeout report.

2.3.8.5 The CRO shall promptly e-mail a copy of each Site Monitoring Report and the follow up letter to RCHSPP/SAIC-Frederick, Inc. and CTM or Lead CRA staff for review and concurrence. Once the Site Monitoring Report and follow-up letter has been approved, the CRO will forward the original monitoring report and a copy of the follow-up letter to RCHSPP/SAIC-Frederick, Inc. for filing in the master file.

2.3.8.6 Following review and approval, the CRO/monitor will forward the original follow up letter to the site within 25 days of the visit date. The letter to the site PI will outline items discussed during the visit and items that need to be addressed.

2.3.8.7 The CRO shall collaborate and communicate effectively with the CTM/Lead CRA and the various components of the research groups, including:

a) Identify any problems that sites are experiencing in implementing protocols and communicate this information in the site visit reports, quarterly progress reports, and conference calls (initially weekly and then every 3-4 weeks) with the CTM or Lead CRA, and recommend solutions as indicated;
b) Provide recommendations, using expertise gained from monitoring and training the sites, for the design and refinement of the research groups' Standard Operating Procedures that are

pertinent to site management, protocol implementation, source documentation, and internal quality management;

c) Have management staff and, if appropriate, the monitors attend the any major meetings as specified by RCHSPP/SAIC-Frederick, Inc.

2.4 Regulatory Compliance and Guidance:

NOTE #8 TO OFFEROR: *It is important that the CRO be familiar with Korean, ICH, and US regulations and has experience in submitting Investigational New Drug (IND) applications (or equivalent) to the Korean FDA. If an IND (or equivalent) is required, the CRO will be responsible for the initial IND (or equivalent) submission to the Korean FDA, the maintenance of the IND (or equivalent) and for submission of additional applicable documents to the Korean FDA as required by the Korean rules and regulations.*

The CRO will review the applicable protocol to determine the appropriate mechanism required for notifying the Korean FDA of the proposed protocol to be in compliance with the Korean rules and regulations. The CRO will determine who the Sponsor of the IND (or equivalent) is or will assume the responsibility of the Sponsor. If required by the Korean FDA, the CRO will be responsible for preparing and submitting an IND (or equivalent) for the clinical research protocol. The CRO will collaborate with RCHSPP/SAIC-Frederick, Inc. to obtain the necessary documents for submission to the Korean FDA.

The CRO will provide RCHSPP/SAIC-Frederick, Inc. with an English translation of the Korean FDA rules and regulations and the Korean ICH guidelines.

2.4.1 The CRO will be responsible for compiling all essential/required documents associated with submitting an initial IND (or equivalent) to the Korean FDA.

2.4.2. The CRO will be responsible for submitting the initial IND (or equivalent) to the Korean FDA in the format required by the Korean rules and regulations.

2.4.3. Once the Korean FDA accepts the IND (or equivalent), it is the responsibility of the CRO to prepare and submit all additional applicable documents to the Korean FDA. This includes protocol amendments, safety information and other documents as required in the Korean rules and regulations.

2.4.4. The CRO is responsible for forwarding a copy of all documents submitted to the Korean FDA to RCHSPP/SAIC-Frederick, Inc.

3. PROJECTED MONITORING VISITS

Study	Number of Monitors	Site Initiation Visit	Number of Monitoring Visits Per Year	Site Closeout Visit
Natural History TB	2	1	3	1
Pimonidazole	1	1	2	1
Metronidazole	1	1	2	1

SECTION D—PACKAGING AND MARKING

ARTICLE D.1. PACKAGING AND SHIPPING

Any deliverables required under this Subcontract, shall be packaged, marked, and shipped in accordance with Government specifications, or as specified herein. At a minimum, all deliverables shall be marked with the Subcontract number and Subcontractor name. The Subcontractor shall guarantee that all required materials be delivered in immediate usable and acceptable condition.

SECTION E—INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

A. The Contracting Officer or a duly authorized representative will perform an evaluation of the research services and acceptance of deliverables provided.

B. For the purposes of this ARTICLE, the SAIC Contracting Officer's Technical Representative (COTR) designated in ARTICLE G.1.is the authorized technical representative of the Contracting Officer.

C. Inspection and acceptance will be performed at the offices of SAIC-Frederick, Inc. Frederick, Maryland.

D. This Subcontract incorporates FAR Clause No. 52-246-9 "Inspection of Research and Development – Short Form by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

SECTION F—DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

A. Unless SAIC-Frederick, Inc. exercises its option set forth below, the Subcontract period of performance shall be from the date of full execution by the Contracting Officer through September 30, 2005 with two (2) Option periods:
Option Period 1 October 1, 2005 through Sep 30, 2006
Option Period 2 October 1, 2006 through Sep 30, 2007

B. Execution of option years will be based upon the SAIC-Frederick's need and the Subcontractor's performance.

C. FAR-52.217-9 Option to Extend the Term of the Contract.

SAIC-Frederick, Inc. may extend the term of this Subcontract by written notice to the Subcontractor within 60 days of the Subcontract end date; provided that SAIC-Frederick, Inc. gives the Subcontractor a preliminary written notice of its intent to extend at least sixty (60 days) before the Subcontract expires. The preliminary notice does not commit SAIC-Frederick, Inc, to an extension.

If SAIC-Frederick, Inc. exercises this option, the extended Subcontract shall be considered to include this option clause.

ARTICLE F.2. DELIVERIES

A Satisfactory performance of the final Subcontract shall be deemed to occur upon performance of the work described in Section C and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of all deliverables and reports.

B. All documentary submissions and presentations shall be in the English language. Translation of documents from Korean into English and from English into Korean will be provided as deemed necessary by SAIC-Frederick.

C. In addition to those reports required by other terms of this Subcontract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with Section F, Article F.2., Deliveries, of this Subcontract.

1. Quarterly Technical Reports

The Contractor shall prepare and submit technical progress reports outlining the work accomplished during each reporting period**. These deliverables shall be submitted on a quarterly basis. The first report is due ninety (90) days from the date of full execution of this Subcontract.** These reports are subject to technical inspection and requests for clarification by the NCI Project Manager.

2. Final Report

Contractor shall submit a Final Report on or before the last day of the Subcontract period. This report will be submitted electronically.

The Final Report shall contain:

(a) Title page to include the following information:
(i) Subcontract number and title
(ii) Period of performance being reported
(iii) Contractor's name and address
(iv) Date of submission

(b) Introduction describing the purpose and scope of the Subcontract effort.

(c) Description of the overall progress during the entire Subcontract tenure to include pertinent data to present significant results achieved.

3. Summary of Results

Contractor shall submit a summary of the results achieved during the performance of this Subcontract. This summary of results shall be submitted with the Final Report.

D. If the Contractor becomes unable to deliver the reports specified hereunder within the period specified, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the SAIC Contracting Officer immediate written notice of anticipated delays with reasons therefore.

E. Copies of all reports identified in ARTICLE C.1 and ARTICLE C.2. shall be submitted to the following addresses:

Report	No. of Copies	Addressee
All Deliverables, Contract/protocol change correspondence/decisions Final Report, etc.	1 copy each	**John Tierney** **Clinical Research Oversight Manager** National Institute of Allergy and Infectious Diseases National Institutes of Health 6700- B Rockledge Drive Bethesda, MD 20817 T: 301-451-5136 F: 301-435-6739 jtierney@niaid.nih.gov
All Deliverables, Contract/protocol change Correspondence/decisions Final Report, etc.	1 copy each	**Susan Vogel** **Clinical Research Oversight Manager** National Institute of Allergy and Infectious Diseases National Institutes of Health 6700 – B Rockledge Drive Bethesda, MD 20817 T: 301-451-5138 F: 301-435-6739 svogel@niaid.nih.gov
All Deliverables, Contract/protocol change correspondence/decisions Final Report, etc.	1 copy each	**Beth Baseler, MS, COTR** **Director of Clinical Monitoring Program** **RCHSPP/SAIC-Frederick, Inc.** National Cancer Institute at Frederick P. O. Box B, Miller Drive, Ft. Detrick 5705 Industry Lane, Room 220 Frederick, MD 21701-8527 T: 301-846-5413 F: 301-846-6188 Email: bbaseler@niaid.nih.gov
All Deliverables, Contract/protocol change correspondence/decisions Final Report, etc.	1 copy each	**Ms. Shelly Simpson, MS** **Assistant COTR, Clinical Trials Manager** **RCHSPP/SAIC Frederick, Inc.** National Institute of Allergy and Infectious Diseases National Institute of Health P. O. Box B, Miller Drive, Ft.Detrick 5705 Industry Lane, Room 223 Frederick, MD 21701-8527 T: 301-846-7508 F: 301-846-6188 Email: ssimpson@niaid.nih.gov
All Deliverables,	1 copy	**Ms. Patty Price-Abbott**

Contract/protocol change correspondence/decisions Final Report, etc.	each	**Assistant COTR, Regulatory Affairs Director** **RCHSPP/SAIC Frederick, Inc.** National Institute of Allergy and Infectious Diseases National Institute of Health P. O. Box B, Miller Drive, Ft.Detrick 21701-8527 T: 301-846-7507 F: 301-846-7514 Email: pprice-abbott@niaid.nih.gov
All Deliverables Contract/protocol change Correspondence/decisions, Final Report, invoicing, etc.	1 copy each	**Eugene B. Anderson** Subcontracts Supervisor SAIC-Frederick, Inc National Cancer Institute at Frederick 92 Thomas Johnson Drive, Suite 250 P. O. Box B, Miller Drive, Fort Detrick Frederick, Maryland 21702-1201 T: 301-228-4006 F: 301-228-4037 Email: eanderson@ncifcrf.gov

ARTICLE F.3. STOP WORK ORDERS

This Subcontract incorporates the following FAR Clause No. 52.245-15 "Stop Work Order with Alternate I by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

SECTION G—CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACT REPRESENTATIVES

A. *Contracting Officer*. The following individual is designated as SAIC's Contracting Officer and is authorized to conduct business, negotiate award and modifications:

Ms. Annette Bishop, MBA, CFCM
Assistant Manager Research Contracts
SAIC-Frederick, Inc.
P. O. Box B, Miller Drive
Fort Detrick
Frederick, MD 21702-1201

Ph: 301-228-4003
Fx: 301-228-4037
E-mail: abishop@ncifcrf.gov

The Contracting Officer is the only person with the authority to act as an agent of the Government under this Subcontract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this Subcontract; or (5) otherwise change any terms and conditions of this Subcontract. All changes in the Statement of Work will be accomplished by bilateral modification to the Subcontract.

1) *Contracting Officer's Technical Representative:*. The following individual is proposed as SAIC's Contracting Officer's Technical Representative (COTR) and is authorized to provide technical guidance and otherwise represent the Government as stated herein:

Beth Baseler, MS
Director of Clinical Monitoring Program
RCHSPP/SAIC-Frederick, Inc.
National Cancer Institute at Frederick
5705 Industry Lane, Room 220
P. O. Box B, Miller Drive Ft. Detrick
Frederick, MD 21701-8527

T: 301-846-5413
F: 301-846-6188
Email: bbaseler@niaid.nih.gov

Ms. Shelly Simpson, MS
Assistant COTR, Clinical Trials Manager
RCHSPP/SAIC Frederick, Inc.
National Institute of Allergy and Infectious Diseases
National Institute of Health
P. O. Box B
Miller Drive, Ft.Detrick
Frederick, MD 21701-8527

T: 301-496-7196
F:301-846-6188
Email: ssimpson@niaid.nih.gov

The Contracting Officer's Technical Representative is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this Subcontract; and (5) assisting in the resolution of technical problems encountered during performance.

B. *Contracts Specialist*. The following individual has been designated as SAIC's Contracts Specialist for purposes of administering, processing and handling contractual documentation:

Mr. Eugene B. Anderson
Supervisor, Subcontracts
SAIC-Frederick, Inc.
National Cancer Institute at Frederick
92 Thomas Johnson Drive
P. O. Box B, Miller Drive, Fort Detrick

Frederick, Maryland 21702-1201
T: 301-228-4008
F: 301-228-4037
eanderson@ncifcrf.gov

C. *Subontractor Authorized Representative(s)*. The following individual(s) is the designated representative of the Company:

TO BE COMPLETED BY OFFEROR

_____
PRINT NAME

_____
TITLE

_____
ORGANIZATION

_____
ADDRESS

_____
ADDRESS

_____
PHONE NUMBER

_____
FAX NUMBER

_____
E-MAIL ADDRESS

D. Subcontractor Authorized Invoice Administrator(s): the following individuals(s) is responsible for preparation and submittal of invoice(s)*:*

TO BE COMPLETED BY OFFEROR

_____
PRINT NAME

_____
TITLE

_____
ORGANIZATION

_____
ADDRESS

_____
ADDRESS

_____
PHONE NUMBER

_____
FAX NUMBER

_____
E-MAIL ADDRESS

ARTICLE G.2. SUBCONTRACTOR KEY PERSONNEL

Pursuant to the Key Personnel clause, HHSAR 352.270-5 incorporated by reference herein, the following individual(s), as employee(s) of Subcontractor, is/are considered to be essential to the work being performed hereunder, and shall not be re-assigned or removed without the concurrence of the Contracting Officer:

`	NAME	TITLE/ADDRESS:
	To Be Completed by Offeror	To Be Completed by Offeror

ARTICLE G.3. INVOICE SUBMISSION

A. Invoices shall be prepared in accordance with the "SAIC/NCI Instructions: Invoice Request and Contract Financial Reporting for Cost Reimbursement Contracts" that is provided as Attachment 2 and submitted as follows:

An original and one (1) copy to the following designated payment office:

Ms. Lori Brooks
SAIC-Frederick, Inc.
National Cancer Institute at Frederick
Research Contracts Department
P. O. Box B, Miller Drive, Fort Detrick
Frederick, Maryland 21702-1201

B. Inquiries regarding payment of invoices should be directed to the attention of Eugene B. Anderson, Supervisor, Subcontracts, at (301) 228-4008.

C. To expedite payment of invoices, it is essential that the Contractor provide sufficient data, as defined in the invoice instructions (See Attachment 2), that will support payment of all costs being billed. For example, a lump sum billing for "Equipment" will not be acceptable, rather, such line item must have the breakdown and itemization stipulated in the invoice instructions under "Preparation and Itemization of the Invoice/Financing Request."

D. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provision as specified in ARTICLE H.1.of this Subcontract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with PL 107-116."

E. Payment shall be considered made on the date for which a check for such payment is dated.

ARTICLE G.4. INDIRECT COST RATES

In accordance with the FAR Clause No. 52.216-7(d)(2), Allowable Cost and Payment, which is incorporated into this Subcontract, indirect cost rates reimbursable hereunder shall be consistent with any Rate Agreements in place between Subcontractor and HHS at the time of execution of this contract. If said agreements expire within the period of performance of this contract Subcontractor is required to provide a new agreement, with effective dates covering the period of performance of this Subcontract. ***or rates previously established as acceptable by Buyer(s).*** The indirect rates negotiated in that agreement are the maximum amounts allowable under this contract until Contractor provides a properly executed superceding rate agreement with HHS. Final approval will be determined by the Contracting Officer.

ARTICLE G.5. GOVERNMENT PROPERTY

The parties agree that no non-expendable property or equipment will be acquired or furnished under this Subcontract, unless prior written authorization is obtained from the Contracting Officer.

ARTICLE G.6. PROGRAM MANAGEMENT AND CONTROL REQUIREMENTS

It is anticipated that meetings with the Contractor may occur as needed to keep the SAIC-Frederick, Inc. COTR and the NCI Project Officer informed regarding the progress of the project. Subcontractor's Principal Investigator will communicate directly with the SAIC-Frederick, Inc. COTR, the SAIC Contract Specialist and the NCI Project Manager by e-mail, fax or other written method, along with telephone and in person when necessary.

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

The Contractor's performance shall be evaluated, and written documentation shall be retained in the Subcontract file.

SECTION H—SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. - PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Subcontractor acknowledges that the U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P. L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract. The full text of the Comprehensive List of Terrorist and Groups identified under Executive Order 13224 can be accessed at:

http://fpc.state.gov/documents/organization/25996.pdf

ARTICLE H.2. SAFETY AND BIOSAFETY STANDARDS

All work performed under this Subcontract shall be conducted in accordance with the Publication entitled, "Biosafety in Microbiological and Biomedical Laboratories" (HHS Publication No. (DCD) 84-8395). This publication can be found at the following addresses:

www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm.
www.orcbs.msu.edu/biological/biolsaf.htm

ARTICLE H.3. HUMAN SUBJECTS

The Subcontractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found a the following web sites:

http://grants.nih.gov/grants/guid/notice-files/not98-084.html
http://grants.nih.gov/grants/guid/notice-files/not99-107.html
http://grants.nih.gov/grants/guid/notice-files/not-od-00-038.html

The Subcontractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract. Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan. The Data and Safety Monitoring (Board and Plan) shall be established and approved by NIAID prior to beginning implementation of any clinical trial.

The Subcontractor is directed to the full text of any and all applicable federal and international regulations cited herein:

1. United States Food and Drug Administration (http://www.fda.gov/oc/gcp/default.htm)
2. Health and Human Services Regulations for Federally Funded Research (http://www.hhs.gov/policies/index.shtml#laws
3. HHSSAR 352-223-70 – Safety and Health (http://www.hhs.gov/ogam/oam/procurement/hhsar.html)
4. Declaration of Helsinki (http://www.wma.net/e/policy/b3.htm)
5. International Conference on Humanization (http://www.ich.org)
6. Ministry of Health of Mali, West Africa
7. United States Code of Federal Regulations: (http://www.gpoaccess.gov/ecfr)
    a. 21 CFR 11, Electronic Records, Electronic Signatures
    b. 21 CFR 50, Human Subject Protection (Informed Consent)
    c. 21 CFR 50, Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products
    d. 21 CFR 54, Financial Disclosure by Clinical Investigators
    e. 21 CFR 56, Institutional Review Boards
    f. 21 CFR 312, Investigational New Drug Application
    g. 45 CFR Part 46, Protection for Human Subjects

ARTICLE H.4. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

Pursuant to Public Law(s) cited in paragraph B., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings, in accordance with P.L.106-554, Section 510.

ARTICLE H.5. NEEDLE EXCHANGE

Pursuant to Public Law(s) cited in paragraph B., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug in accordance with P.L. 106-554, Section 505.

ARTICLE H.6. ANIMAL WELFARE ASSURANCE

The Subcontractor shall obtain, prior to the start of any work utilizing laboratory animals under this Subcontract, an approved Animal Welfare Assurance from the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Subcontractor shall maintain such assurance for the duration of this Subcontract, and any Subcontractors performing work under this Subcontract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.

ARTICLE H.7. RECORDS OF COMPLIANCE

The Subcontractor shall provide copies of the USDA (United States Department of Agriculture) Reports of Inspection of Animal Facilities, Sites or Premises, VS Form 18.8; semiannual reports of ACUC (Animal Care and Use Committee) evaluations required to be filed by PHS (Public Health Service) Policy; and other reports sent to OLAW (Office of Laboratory Animal Welfare; formerly OPRR, Office of Protection from Research Risks) in fulfillment of requirements of PHS Policy.

ARTICLE H.8. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

Under governing policy, federal funds administered by the Public Health Service (PHS) shall not be expended for research involving live vertebrate animals without prior approval by the Office of Laboratory Animal Welfare (OLAW), of an assurance to comply with the PHS policy on humane care and use of laboratory animals. This restriction applies to all performance sites (e.g. collaborating institutions, Subcontractors, sub-grantees) without OLAW-approved assurances, whether domestic or foreign.

ARTICLE H.9. SALARY RATE LIMITATION LEGISLATION PROVISIONS

A. Pursuant to Public Law(s) cited in paragraph B., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown for the fiscal year covered. Direct salary is exclusive of overhead, fringe benefits and general and administrative expenses.

B. The per year salary rate limit also applies to individuals proposed under Subcontracts. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts in accordance with PL 107-116.

Effective January, 2004,, this amount is **$175,700 and will remain at this level until such time as the Executive Level I is increased. See the web site listed below for FY-2003 Executive Level I rates of pay. FY03 Executive Level Salaries:* http://www.opm.gov/oca/04tables/html/ex.asp

ARTICLE H.10. PUBLICATION AND PUBLICITY

The Subcontractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this Subcontract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal Funds from the National Cancer Institute, National Institutes of Health, under Contract No. NO1-CO-12400."

ARTICLE H.11. PRESS RELEASES

Pursuant to Public Law(s) cited in paragraph B., below, the Subcontractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources in accordance with P.L. 106-554, Section 507.

ARTICLE H.12. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on (http://www.od.nih.gov/oma/manualchapters/management/1754).

ARTICLE H.13. ORGANIZATIONAL CONFLICT OF INTEREST

During the performance of this Subcontract, the Subcontractor is prohibited from engaging in similar work or services adverse to the interests of SAIC/NCI. The Subcontractor also certifies that no services rendered under any agreement during the term of this contract will be adverse to the interest of SAIC/NCI. The Subcontractor also certifies that no financial, contractual, organizational, or other interest exists relating to the work under this agreement that would constitute an Organizational Conflict of Interest or otherwise cause the Subcontractor to be unable or potentially unable to render impartial assistance or advice, impair objectivity in performing the work, or create an unfair competitive advantage for any entity wherein the Subcontractor has an interest. The Federal statutes and regulations concerning conflict of interest carry criminal penalties for violation. The Subcontractor is personally responsible for identifying any such conflict of interest, or any relationship or actions that might give the appearance that a conflict of interest exists or could reasonably be viewed as affecting the Subcontractor's objectivity in performing the work under this agreement. By signature the Subcontractor certifies the understanding of the above and that no Organizational Conflict of Interest exists that would affect this Subcontract. The Subcontractor also indemnifies or otherwise holds harmless SAIC/NCI should an Organizational Conflict of Interest become apparent (not previously disclosed) during the life of this Subcontract.

ARTICLE H.14. HOTEL AND MOTEL FIRE SAFETY ACT OF 11990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in , or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be assessed at: http://www.usfa.fema.gov/hotel/index.htm

ARTICLE H.15. INSURANCE REQUIREMENTS AND CERTIFICATES

The Subcontractor must provide Certificates of Insurance, proving:

a) Commercial General Liability coverage
b) Errors & Omissions coverage
c) Professional Liability coverage
d) Property Damage coverage
e) Automobile Liability coverage
f) All Risk coverage
g) Worker's Compensation coverage
h) Foreign Workers' Compensation coverage (including Defense Base Act coverage)

The Certificate of Insurance shall certify that the Subcontractor is insured for the period of performance of this Subcontract. Further, the Certificate of Insurance shall name SAIC-Frederick, Inc., as ***"Additionally Named Insured."*** The contract number and name of the project shall be included in the block naming SAIC-Frederick, Inc. as Additional Named Insured.

If at any time of the period of performance of this Subcontract the insurance coverage lapses or is cancelled, the Subcontractor will immediately notify SAIC-Frederick, Inc., and take appropriate measures to replace or renew required coverages, providing appropriate replacement Certificate of Insurance.

PART II – CONTRACT CLAUSES
SECTION I—CONTRACT CLAUSES

ARTICLE I.1.A: GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT, RESEARCH AND DEVELOPMENT.

Where the words "*Contracting Officer*" or "*Government*" appear, it shall be understood to mean "*SAIC Contracting Officer*" or "*Prime Contractor*" provided; however, that such substitution in no way supersedes or diminishes any rights or responsibilities of the Government under public law, Federal Acquisition Regulations, or in the terms of the prime contract, including, but not limited to, the right to review, audit, and approve any records or procedures of the Subcontractor. Where the word "*Contractor*" appears, it shall be understood to mean "*Subcontractor*" and where "*Contract*" appears, it shall be understood to mean "*Subcontract*."

This Subcontract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

GENERAL CLAUSES

Negotiated Cost-Plus Fixed Fee Research and Development Contract			
Reg	**Clause**	**Date**	**Clause Title**
FAR	52.202-1	Jul 2004	Definitions
FAR	52.203-3	Apr 1984	Gratuities (Over $100,000)
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
FAR	52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
FAR	52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
FAR	52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
FAR	52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
FAR	52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
FAR	52.214-34	Apr 1991	Submission of Offers in the English Language
FAR	52.214-35	Apr 1991	Submission of Offers in US Currency
FAR	52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
FAR	52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
FAR	52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-12	Oct 1997	Subcontractor Cost or Pricing Data
FAR	52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
FAR	52.215-15	Jan 2004	Pension Adjustments and Asset Reversions
FAR	52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
FAR	52.216-7	Dec 2002	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee
FAR	52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
FAR	52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a)

Negotiated Cost-Plus Fixed Fee Research and Development Contract			
Reg	**Clause**	**Date**	**Clause Title**
			of this clause is $0 unless otherwise specified in the contract.)
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-26	Apr 2002	Equal Opportunity
FAR	52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-14	Jun 2003	Toxic Chemical Release Reporting
FAR	52.225-1	Jun 2003	Buy American Act – Supplies
FAR	52.225-13	Dec 2003	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
FAR	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
FAR	52.227-3	Apr 1984	Patent Indemnity
FAR	52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
FAR	52.227-14	Jun 1987	Rights in Data – General
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	Jun 1996	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232.22	Apr 1984	Limitation of Funds
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
FAR	52.233.1	Jul 2002	Disputes
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	Mar 2001	Penalties for Unallowable Costs (Over $500,000)
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy (Over $100,000)
FAR	52.242-15	Aug 1989	Stop Work Order w/ Alternate 1 (Apr 1984) Substitute “30” days for all “60” day periods
FAR	52.243.2	Aug 1987	Changes – Cost Reimbursement
FAR	52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to Subcontract is required, the identified Subcontracts are listed in ARTICLE B, Advance Understandings.
FAR	52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
FAR	52.244-6	May 2001	Subcontracts For Commercial Items
FAR	52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
FAR	52.246-5	Apr 1984	Inspection of Services – Cost Reimbursement
FAR	52.246.9	Apr 1984	Inspection of Research and Development (Short Form)
FAR	52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
FAR	52.246-24	Feb 1997	Limitation of Liability – High Value Items
FAR	52.246-25	Feb 1997	Limitation of Liability (Over $100,00) (Services)
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays

Negotiated Cost-Plus Fixed Fee Research and Development Contract			
Reg	**Clause**	**Date**	**Clause Title**
FAR	52.253-1	Jan 1991	Computer Generated Forms

ARTICLE I.1.B: HHS CLAUSES

This Subcontract incorporates the following DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION HHSAR 48 Chapter 3 clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.hhs.gov/ogam/oam/procurement/hhsar.html

HHSAR	352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
HHSAR	352.216-72	Oct 1990	Additional Cost Principles
HHSAR	352.223-70	Jan 2001	Safety and Health
HHSAR	352.224-70	Apr 1984	Confidentiality of Information
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.249-14	Apr 1984	Excusable Delays
HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-1	Jan 2001	Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act
HHSAR	352.270-8	Jan 2001	Protection of Human Subjects

ARTICLE I.1.C: ADDITIONAL CLAUSES INCLUDED IN FULL TEXT

This Subcontract incorporates the following clauses in full text:

HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) CLAUSE:

HHSAR 352.228-7 Insurance Liability to third persons (Cost Reimbursement contract)

As prescribed in 328.311-2, contracting officers shall include the following clause in all cost-reimbursement contracts, in lieu of the clause at FAR 52.228-7:

Insurance--Liability to Third Persons (Dec. 1991)

(a) (1) Except as provided in paragraph (a)(2) immediately following, or in paragraph (h) of this clause (if the clause has a paragraph (h)), the Contractor shall provide and maintain workers' compensation, employer's liability, comprehensive general liability (bodily injury), comprehensive automobile liability (bodily injury and property damage) insurance, and such other insurance as the Contracting Officer may require under this contract.

(2) The Contractor may, with the approval of the Contracting Officer, maintain a self-insurance program; provided that, with respect to workers' compensation, the Contractor is qualified pursuant to statutory authority.

(3) All insurance required by this paragraph shall be in form and amount and for those periods as the Contracting fficer may require or approve and with insurers approved by the Contracting Officer.

(b) The Contractor agrees to submit for the Contracting Officer's approval, to the extent and in the manner required by the Contracting Officer, any other insurance that is maintained by the Contractor in connection with performance of this contract and for which the Contractor seeks reimbursement.

(c) Except as provided in paragraph (h) of this clause (if the clause has a paragraph (h)), the Contractor shall be reimbursed:
(1) For that portion of the reasonable cost of insurance allocable to this contract, and required or approved under this clause; and

(2) For certain liabilities (and expenses incidental to such liabilities) to third persons not compensated by insurance or otherwise within the funds available under the Limitation of Cost or the Limitation of Funds clause of this contract. These liabilities must arise out of the performance of this contract, whether or not caused by the negligence of the Contractor or the Contractor's agents, servants, or employees, and must be represented by final judgments or settlements approved in writing by the Government. These liabilities are for:
(i) Loss of or damage to property (other than property owned, occupied, or used by the Contractor, rented to the Contractor, or in the care, custody, or control of the Contractor); or
(ii) Death or bodily injury.

(d) The Government's liability under paragraph (c) of this clause is limited to the amounts reflected in final judgements, or settlements approved in writing by the Government, but in no event to exceed the funds available under the Limitation of Cost or Limitation of Funds clause of this contract. Nothing in this contract shall be construed as implying that, at a later date, the Government will request, or the Congress will appropriate, funds sufficient to meet any deficiencies.

(e) The Contractor shall not be reimbursed for liabilities (and expenses incidental to such liabilities):
(1) For which the Contractor is otherwise responsible under the express terms of any clause specified in the Schedule or elsewhere in the contract:
(2) For which the Contractor has failed to insure or to maintain insurance as required by the Contracting Officer; or
(3) That result from willful misconduct or lack of good faith on the part of the Contractor's directors, officers, managers, superintendents, or other representatives who have supervision or direction of:
(i) All or substantially all of the Contractor's business;
(ii) All or substantially all of the Contractor's operations at any one plant or separate location in which this contract is being performed; or
(iii) A separate and complete major industrial operation in connection with the performance of this contract.

(f) The provisions of paragraph (e) of this clause shall not restrict the right of the Contractor to be reimbursed for the cost of insurance maintained by the Contractor in connection with the performance of this contract, other than insurance required in accordance with this clause; provided, that such cost is allowable under the Allowable Cost and Payment clause of this contract.

(g) If any suit or action is filed or any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, and the risk of which is then uninsured or is insured for less than the amount claimed, the Contractor shall:
(1) Immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received;
(2) Authorize Government representatives to collaborate with counsel for the insurance carrier in settling or defending the claim when the amount of the liability claimed exceeds the amount of coverage; and
(3) Authorize Government representatives to settle or defend the claim and to represent the Contractor in or to take charge of any litigation, if required by the Government, when the liability is not insured or covered by the bond. The Contractor may, at its own expense, be associated with the Government representatives in any such claim or litigation.

(End of clause)

FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSE:

FAR 52.244-6 SUBCONTRACTS FOR COMMERCIAL ITEMS MAY 2001

(a) *Definitions.* As used in this clause—
"Commercial item" has the meaning contained in the clause at 52.202-1, Definitions.
"Subcontract" includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or Subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its Subcontractors at all tiers to incorporate, commercial items or non-developmental items as components of items to be supplied under this contract.

(c) (1) The following clauses shall be flowed down to Subcontracts for commercial items:
(i) 52.219-8, Utilization of Small Business Concerns (Oct 2000) (15 U.S.C. 637(d)(2) and (3)), in all Subcontracts that offer further Subcontracting opportunities. If the Subcontract (except Subcontracts

to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the Subcontractor must include 52.219-8 in lower tier Subcontracts that offer Subcontracting opportunities.

(ii) 52.222-26, Equal Opportunity (Feb 1999) (E.O. 11246).

(iii) 52.222-35, Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (Apr 1998) (38 U.S.C. 4212(a)).

(iv) 52.222-36, Affirmative Action for Workers with Disabilities (Jun 1998) (29 U.S.C. 793).

(v) 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (Jun 2000) (46 U.S.C. Appx 1241) (flowdown not required for Subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to Subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in Subcontracts awarded under this contract.

(END OF CLAUSE)

ARTICLE I.1.D: SAIC TERMS AND CONDITIONS

1. GOVERNMENT RELATIONSHIP

This Order is made by SAIC-Frederick, Inc., a Subsidiary of Science Applications International Corporation under its contract with the National Cancer Institute at Frederick (NCI-Frederick). The provisions and clauses contained herein are influenced by and reflect the relationship of the parties in that contract, which was awarded and is administered under the provision of the Federal Acquisition Regulation (FAR). There is no privity of contract between the Seller and the Government.

2. GENERAL RELATIONSHIP

The Seller is not an employee of SAIC-Frederick, Inc. for any purpose whatsoever. Seller agrees that in all matters relating to this Order it shall be acting as an independent contractor and shall assume and pay all liabilities and perform all obligations imposed with respect to the performance of this Order. Seller shall have no right, power or authority to create any obligation, expressed or implied, on behalf of Buyer and/or Buyer's customers and shall have no authority to represent Buyer as an agent.

3. DEFINITIONS

Buyer – SAIC-Frederick, Inc.

Seller – The party (contractor) receiving the award from SAIC-Frederick, Inc.

Contracting Officer – The SAIC-Frederick, Inc. person with the authority to enter into and administer Orders. The term includes authorized representatives of the Contracting Officer acting within their delegated authority.

Order – The contractual agreement between SAIC-Frederick, Inc. and the Seller.

Special Definitions – See paragraph 4 for the special definitions that apply in the use of the solicitation and award clauses of this Order.

4. SOLICITATION AND AWARD CLAUSES – SPECIAL DEFINITIONS

FAR clauses included in this Order, including any solicitation document, shall be interpreted as follows:

Unless a purposeful distinction is made clear and the context of the clause requires retention of the original definition, the term "Contractor" shall mean Seller, the term "Contract" shall mean this Order, the term "Subcontractor" shall mean Subcontractors of Seller at any tier, and the terms "Government", "Contracting Officer" and equivalent phrases shall mean SAIC-Frederick, Inc. and SAIC-Frederick's Contracting Officer, respectively. It is intended that the referenced clauses shall apply to Seller in such manner as is necessary to reflect the position of Seller as a contractor to SAIC-Frederick, Inc. to insure Seller's obligations to SAIC-Frederick, Inc. and to the United States Government, and to enable SAIC-Frederick, Inc. to meet its obligations under its Prime Contract.

Full text of the referenced clauses may be found in the FAR (Code of Federal Regulation [CFR] Title 48), obtainable from the Superintendent of Documents, Government Printing Office (GPO), Washington, DC 20402 or online at http://www.arnet.gov/far/.

Copies of the clauses will be furnished by the Contracting Officer upon request.

5. ENTIRE AGREEMENT

This Order, including all attachments and/or documents incorporated by reference by Buyer, shall constitute the entire agreement between Buyer and Seller. No other document (including Seller's proposal, quotation or acknowledgement forms, etc.) shall be a part of this order, even if referred to, unless specifically agreed to in writing by Buyer. No right that Buyer has regarding this Order may be waived or modified except in writing by Buyer.

6. ACCEPTANCE AND MODIFICATION OF TERMS

Acceptance of this Order by Seller may be made by signing the acknowledgement copy hereof or by partial performance hereunder, and any such acceptance shall constitute an unqualified agreement to all terms and conditions set forth herein unless otherwise modified in writing by the parties. Any additions, deletions or differences in the terms proposed by Seller are objected to and hereby rejected, unless Buyer agrees otherwise in writing. No additional or different terms and conditions proposed by the Seller in accepting this Order shall be binding upon Buyer unless accepted in writing by Buyer and no other addition, alteration or modification to, and no waiver of any of the provisions herein contained shall be valid unless made in writing and executed by Buyer and Seller. Seller shall perform in accordance with the Description/Quantity schedule set forth in this Order an all attachments thereto.

7. LEGAL CONSTRUCTION AND INTERPRETATIONS

This Order shall be governed by and interpreted in accordance with the principles of Federal Contract Law, and to the extent that Federal Contract Law is not dispositive, and the state law becomes applicable, the law of the State of Maryland shall apply.

8. COMPLIANCE WITH LAWS AND REGULATIONS

Seller shall submit all certifications required by Buyer under this Order and shall at all times, at its own expense, comply with all applicable Federal, State and local laws, ordinances, administrative orders, rules or regulations.

9. GIFTS

Seller shall not make or offer a gratuity or gift of any kind to Buyer's employees or their families. Seller should note that the providing of gifts or attempting to provide gifts under government Subcontracts might be a violation of the Anti-Kickback Act of 1986 (4 U.S.C. 51-58).

10. MARYLAND SALES AND USE TAX

The State of Maryland has issued Direct Payment Permit #3 to SAIC-Frederick, Inc. for all vendor purchases for the NCI-Frederick effective August 29, 1996. A copy of this certificate is available to vendors upon request. SAIC-Frederick, Inc. is authorized to make direct payment of sales and use tax to the State of Maryland and vendors are not to add sales tax to invoices, nor are they responsible for collection of such taxes for purchases by SAIC-Frederick, Inc. for the NCI-Frederick after the above date.

11. BUYER FURNISHED DATA AND MATERIALS

All data and materials furnished by Buyer to Seller under this Order including drawings, specifications and written information and Buyer-owned parts and/or Buyer-owned tools and equipment shall be used solely for the work to be performed under this Order. Seller shall repair and maintain all tools at its own expense unless agreed to otherwise. Seller agrees to promptly return all such data and materials upon completion of the work or termination of this Order. Seller agrees to return all materials in the same condition as delivered to Seller, reasonable wear and tear excepted.

12. NOTICE OF DELAY

Seller agrees to immediately notify Buyer in writing of any actual or potential delay in Sellers performance under this Order. Such notice shall, at a minimum, describe the cause, effect, duration and corrective action proposed by Seller to address the problem. Seller shall give prompt written notice to the Buyer of all changes to such conditions.

13. CHANGES AND SUSPENSION

Buyer may, by written notice to Seller at any time, make changes within the general scope of this Order in any one or more of the following: (a) drawings, designs or specifications; (b) quantity; (c) time or place of delivery; (d) method of shipment or packing; and (e) the quantity of Buyer furnished property. Buyer may, for any reason, direct Seller to suspend, in whole or in part,

delivery of goods or performance of services hereunder for such period of time as may be determined by Buyer in its sole discretion. If any such change or suspension causes a material increase or decrease in the cost of, or the time required for the performance of any part of the work under this Order, an equitable adjustment shall be made in the Order price or delivery schedule, or both, provided Seller shall have notified Buyer in writing of any claim for such adjustment within twenty (20) days from the date of notification of the change or suspension from Buyer. No such adjustment or any other modification of the terms of this Order will be allowed unless authorized by Buyer by means of a written modification to the Order. Seller shall proceed with the work as changed without interruption and without awaiting settlement of any such claim.

14. ADVERTISING

Seller agrees that prior to the issuance of any publicity or publication of any advertising that in either case makes reference to this Order, or to Buyer, Seller will obtain the written permission of Buyer with respect thereto.

15. CONFIDENTIAL INFORMATION

Seller shall not at any time, even after the expiration or termination of this Order, use or disclose to any person for any purpose other than to perform this Order, any information it receives, directly or indirectly from Buyer in connection with this Order, except information that is or becomes publicly available, or is rightfully received by Seller from a third party without restriction. Upon request by Buyer, Seller shall return to Buyer all documentation and other material containing such information.

Seller shall not disclose to Buyer any information that it deems to be confidential or proprietary, and it is understood that no information received by Buyer, including manuals, drawings and documents, will be of a confidential nature or restrict in any manner the use or disclosure of such information by Buyer. Seller agrees that any legend or other notice on or pertaining to any information or materials supplied by it that is inconsistent with the preceding sentence shall create no obligation on the part of Buyer.

16. INDEMNIFICATION

Seller shall indemnify, defend and hold harmless Buyer from and against any and all claims, liabilities, damages, losses, causes of action, lawsuits, costs and expenses, including reasonable attorneys' fees and litigation costs incurred in connection therewith and regardless of legal theory (hereinafter referred to as "claims"), occasioned wholly or in part by any act or omission of Seller or any of its lower tiers, or their employees, agents or representatives arising out of or relating to this Order. Notwithstanding the foregoing, Seller's obligations under this Section shall not apply to any claims that are finally determined by a court of competent jurisdiction to be occasioned solely by the negligence or willful misconduct of Buyer.

17. INFRINGEMENT INDEMNITIES

Seller shall indemnify, defend and hold Buyer and Buyer's customers (hereinafter collectively referred to as "Buyer") harmless from and against any claim, suit or proceeding ("claim") brought against Buyer asserting that the goods or services, or any part thereof, furnished under this Order, or Buyer's use (including resale) thereof, constitutes an infringement of any patent, trademark, trade secret, copyright or other intellectual property right, and Seller shall pay all damages and costs awarded against and reasonable expenses incurred by Buyer in connection with such claim including reasonable attorneys' fees. In the event such goods or services or use thereof are enjoined in whole or in part, Seller shall at its expense and option undertake one of the following: (i) obtain for Buyer the right to continue the use of such goods or services; (II) in a manner acceptable to Buyer, substitute equivalent goods or services or make modifications thereto so as to avoid such infringement and extend this indemnity thereto; or (III) refund to Buyer an amount equal to the purchase price for such goods or services plus any excess costs or expenses incurred in obtaining substitute goods or services from another source.

18. NON-WAIVER OR RIGHTS

The failure of Buyer to insist upon strict performance of any of the terms and conditions in this Order or to exercise any rights or remedies, shall not be construed as a waiver of its rights to assert any of same or to rely on any such terms or conditions at any time thereafter. Any rights and remedies specified under this Order shall be cumulative, non-exclusive and in addition to any other rights and remedies available at law or equity. The invalidity in whole or in part of any term or condition of this Order shall not affect the validity of other parts thereof.

19. INSURANCE REQUIREMENTS-FOR WORK ON A GOVERNMENT INSTALLATION

If this Order entails effort on a Government installation, including any off-site buildings owned or leased by the Government, the Seller must provide and maintain the minimum amounts of insurance stated below.

At Buyer's request, Seller agrees to provide Certificates of Insurance evidencing that the required insurance coverages are in force and providing not less than thirty days written notice prior to any cancellation or restrictive modification of the policies.

Further, the required insurance coverages below shall be primary and non-contributing with respect to any other insurance that may be maintained by Buyer. The below required coverages and their limits in no way lessen nor affect Seller's other obligations or liabilities set forth in this Order.

Seller agrees to purchase and maintain at its own expense the following insurance coverages with minimum limits as stated:

(i) Statutory Workers' Compensation and Employer's Liability in an amount no less than $1 Million per occurrence covering its employees, including a waiver of subrogation obtained from the carrier in favor of Buyer;

(ii) Commercial General Liability in an amount no less than $1 Million per each occurrence and $2 Million in this Aggregate covering bodily injury, broad form property damage, personal injury, products and completed operations, contractual liability and independent contractors' liability. Buyer, its officers and employees shall be included as Additional Insureds and a waiver of subrogation shall be obtained from the carrier in favor of Buyer;

(iii) Automobile Liability in an amount no less than $1 Million Combined Single Limit for Bodily Injury covering use of all owned, non-owned, and hired vehicles. Buyer, its officers and employees shall be included as Additional Insureds on the policy;

(iv) Professional Liability in an amount no less than $1 Million per occurrence covering damages caused by any acts, errors, and omissions arising out of the professional services performed by Seller, or any person for whom the Seller is legally liable. To the extent that coverage for Seller's services are no excluded in (ii) above by virtue of being deemed not of a professional nature, this requirement does not apply.

(v) All-Risk Property Insurance in an amount adequate to replace property, including supplies covered by this Order, of Buyer and/or Buyer's customer that may be in the possession or control of Seller. Buyer shall be named as a Loss Payee with respect to loss or damage to said property and/or supplies furnished by Buyer.

20. EXPORT CONTROL COMPLIANCE FOR FOREIGN PERSONS

Seller shall not, nor shall Seller authorize or permit its employees, agents or lower tiers to disclose, export or re-export any Buyer information, or any process, product or service that is produced under this Order, without prior notification to Buyer and complying with all applicable Federal, State and local laws, regulations and ordinances, including the regulations of the U.S. Department of Commerce and/or the U.S. Department of State. In addition, Seller agrees to immediately notify Buyer if Seller is listed in the Table of Denial Orders published by the Department of Commerce, or it Seller's export privileges are otherwise denied, suspended or revoked in whole or in part.

The subject technology of this Subcontract (together including data, services, and hardware provided hereunder) may be controlled for export purposes under the International Traffic in Arms Regulations (ITAR) controlled by the U.S. Department of State or the Export Administration Regulations ("EAR") controlled by the U.S. Department of Commerce. ITAR controlled technology may not be exported without prior written authorization and certain EAR technology requires a prior license depending upon its categorization, destination, end-user and end-use. Exports of any U.S. technology to Iran, Iraq, Libya, North Korea, Sudan, Cuba, and other destinations under U.S. sanction or embargo are forbidden.

Access to certain technology ("Controlled Technology") by Foreign Persons (working legally in the U.S.), as defined below, may require an export license if the Controlled Technology would require a license prior to delivery to the Foreign Person's country of origin. SELLER is bound by U.S. export statutes and regulations and shall comply with all U.S. export laws. SELLER shall have full responsibility for obtaining any export licenses or authorization required to fulfill its obligations under this Subcontract.

SELLER hereby certifies that all SELLER employees who have access to the Controlled Technology are U.S. citizens, have a valid green card or, have been granted political asylum or refugee status in accordance with 8 U.S.C. 1324b(a)(3). Any non-citizens who do not meet one of these criteria are "Foreign Persons" within the meaning of this clause and have been authorized under export licenses to perform their work hereunder.

21. ASSIGNMENT

Neither this Order nor any interest herein may be assigned, in whole or in part, without the prior written consent of Buyer except that the Seller shall have the right to assign this Order to any successor of such party by way of merger or consolidation or the acquisition of substantially all of the business and assets of the Seller relating to the subject matter of this Order. This right shall be retained provided that such successor shall expressly assume all of the obligations and liabilities of the Seller under this Order, and that the Seller shall remain liable and responsible to Buyer for the performance and observance of all such obligations.

Notwithstanding the foregoing, any amounts due the Seller may be assigned in accordance with the provisions of the clause 52.232-23, Assignment of Claims.

In the event the prime contract of SAIC-Frederick, Inc. with the Government is succeeded by a successor contractor selected by the Government, this Order may be assigned to the successor contractor.

22. DISPUTES

Buyer and Seller agree to first enter into negotiations to resolve any controversy, claim or dispute ("dispute") arising under or relating to this Order. The parties agree to negotiate in good faith to reach a mutually agreeable resolution of such dispute within a reasonable period of time. If good faith negotiations are unsuccessful, Buyer and Seller agree to resolve the dispute by binding and final arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association then in effect. The arbitration shall take place in the County of Frederick, State of Maryland. The arbitrator(s) shall be bound to follow the provisions of this Order in resolving the dispute, and may not award punitive damages. The decision of the arbitrator(s) shall be final and binding on the parties, and any award of the arbitrator(s) may be entered or enforced in any court of competent jurisdiction.

Pending any decision, appeal or judgment referred to in this provision or the settlement of any dispute arising under this Subcontract, Seller shall proceed diligently with the performance of this Subcontract.

23. NOTIFICATION OF DEBARMENT/SUSPENSION

By acceptance of this Order either in writing or by performance, Seller certifies that as of the date of award of this Order neither the Seller, lower tiers, nor any of its principals, is debarred, suspended, or proposed for debarment by the Federal Government. Further, Seller shall provide immediate written notice to the Buyer in the event that during performance of this Order the Seller or any of its principals is debarred, suspended, or proposed for debarment by the Federal Government.

24. QUALITY ASSURANCE

The Buyer, and/or personnel authorized by Buyer, shall have the right, at all reasonable times, to visit Seller's facilities or such parts thereof as may be engaged in work relating to this Order in order to verify that Seller's performance is in accordance with all requirements of this Order. In addition, the Buyer, and/or personnel authorized by Buyer, shall have the right, at all reasonable times, to visit the facilities of the Seller's lower tiers or such parts thereof as may be engaged in work relating to this Order. The Seller shall include a like provision in all related lower-tier Subcontracts. Nothing herein shall give the Buyer the right to issue direct orders or instructions to Seller's lower tiers. Seller shall be furnished prior notice of any planned visit.

25. ORDER OF PRECEDENCE

In the event of an inconsistency or conflict between these SAIC Terms and Conditions and the Order issued, the inconsistency or conflict shall be resolved by giving precedence in the following order:

1) The Order and any provisions.

2) SAIC-Frederick, Inc. Standard Terms and Conditions and Exhibits thereto.

3) Specifications and/or drawings.

4) Other documents or exhibits when attached.

26. TERMINATION

Buyer may terminate this Order (in whole or in part) for convenience or for cause pursuant to the Federal Acquisition Regulation Part 49, "Terminations of Contracts" and/or the provisions of the individual Order.

27. SECURITY

Under its contract with NCI-Frederick, SAIC-Frederick, Inc. may be required to conduct, on persons performing work on Government Owned or controlled installations, individual background checks prior to the commencement of effort. As part of this process, information will be required to enable SAIC-Frederick, Inc., to conduct the appropriate background checks, including name (including any aliases), daytime phone number, SSN, date of birth, and country of birth. Individuals who are unable or unwilling to provide the required information and/or receive the required authorizations will not be allowed access to NCI-Frederick or any controlled premises.

(END OF SAIC TERMS AND CONDITIONS)

PART III—LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J—LIST OF ATTACHMENTS

ARTICLE J.1: ATTACHMENTS

1. Cost Estimate Worksheet – Financial Analysis
2. SAIC/NCI Instructions: Invoice Request and Contract Financial Reporting for Cost-Reimbursement Contracts
3. Part IV–Section K: Representations, Certifications & Other Statements

PART IV — REPRESENTATIONS, CERTIFICATIONS AND OTHER STATESMENTS OF OFFERORS

SECTION K— REPRESENTATIONS, CERTIFICATIONS AND OTHER STATESMENTS OF OFFERORS

ARTICLE K.1: REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

This document is provided as Attachment 3. All pages must be completed and submitted with the Subcontractor's proposal. At time of award, the Representations and Certifications made by the Subcontractor shall be physically removed from the award document and incorporated by reference. The originals shall be retained as part of the SAIC contract file.

PART V — INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS
SECTION L— INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

ARTICLE L.1 TYPE OF CONTRACT (FAR 52.216-1) APR 1984

SAIC-Frederick, Inc. intends to award Cost-Plus-Fixed-Fee or Time and Material type Subcontract(s) resulting from this Solicitation. Any resultant contract shall include the clauses applicable to the selected Offeror's organization and type of contract awarded as required by Public Law, Executive Order or acquisition regulations in effect at the time of execution of the proposed contract.

ARTICLE L.2. PREPARATION COSTS:

This RFP does not commit SAIC-Frederick, Inc., or the Government to pay for the preparation and submission of a proposal.

ARTICLE L.3. PROPOSAL PREPARATION INSTRUCTIONS

A. Authorizing Official:

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP.

B. Format:

1. In order to provide all necessary information for a comprehensive evaluation, your proposal shall be submitted as follows:

Volume I - Technical Proposal	original and eight (8) copies
Volume II – Management Proposal	original and eight (8) copies
Volume III – Cost Proposal	original and eight (8) copies

2. Pricing data relating to indirect cost rates or amounts, fee amounts (if any), and total costs, **SHALL NOT** be shown in the forwarding letter or in the technical proposal, however, this data shall be included in the cost proposal.

3. Technical Proposals shall not exceed 50 typewritten pages, single spaced, double-sided, utilizing "Times New Roman" 10pt font, with one inch (1") top and side margins, reproduced on letter size (8 ½ x 11) paper. Key staff curriculum vitae do not count against the page limitation.

4. Elaborate brochures or other presentations beyond those sufficient to present a complete and effective response to the RFP are not desired.

5. SAIC-Frederick reserves the right to award a contract based on initial offer received, without discussion of such offer. Accordingly, each initial offer should be submitted on the most favorable terms from a technical and price standpoint.

6. Proposal preparation costs are the responsibility of the Offeror.

7. **ALL PROPOSALS MUST BE RECEIVED BY MONDAY, November 15, 2004, 2:00 P.M., EASTERN DAYLIGHT TIME. All proposals must be received by Federal Express or United Parcel Service. Do not 'waive signature' on any air bill. All proposals must be delivered to:**

Eugene B. Anderson
Supervisor, Subcontracts
SAIC-Frederick, Inc.
92 Thomas Johnson Drive
Suite 250
Frederick, MD 21702
301-228-4008
eanderson@ncifcrf.gov

8. ALL QUESTIONS OR REQUESTS FOR CLARIFICATIONS MUST BE RECEIVED BY Eugene B. Anderson, SAIC-Frederick, Inc., BEFORE 2:00 P.M., EDT, October 29, 2004. Questions or requests directed to any other individual or outside the directives of this solicitation will not be considered valid.

ARTICLE L.4. VOLUME I -- TECHNICAL PROPOSAL PREPARATION INSTRUCTIONS

A. The technical proposal shall reflect a clear understanding of the proposed work and your proposed method of attaining contract objectives. In order to achieve the objectives stated in the scope of work, Section C, the proposal shall demonstrate experience in and plans for all tasks necessary to achieve completion of the Scope of Work, Section C.

B. To facilitate the evaluation, the technical proposal should be sufficiently detailed and complete to clearly demonstrate that the Offeror has a thorough understanding of the contract requirements. It is realized that all of the technical factors cannot be detailed in advance; however, the technical proposal shall contain sufficient detail to indicate the proposed means for complying with all applicable specifications, and shall include:

1. Experience, expertise and skills of the Offeror as demonstrated by submissions such as previous work experiences for similar projects. (Curriculum vitaes of assigned personnel are required, Article L.5, Volume II, Management Proposal Instructions).

2. How the project is to be organized, staffed, and managed;

3. Procedures to be exercised, along with proposed milestone schedules;

4. Direct resources information such as labor hours and categories, subcontracts, travel, etc., so that the Offeror's understanding of the project may be evaluated. The technical proposal, however, *shall **not** include pricing data relating to any of these costs, including but not limited to indirect cost rates or amounts, fee amounts (if any) and total costs. All cost information for all line items must be proposed separately in the Volume III, Cost Proposal.*

5. Describe in detail the methodologies you will use for the project, indicating any areas of anticipated difficulties, and any unusual expenses you anticipate.

6. Schedule: Provide a schedule for completion of the work and delivery of items specified in the Statement of Work, Section C. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar weeks and months, from the date of authorization to proceed. Use of Microsoft Project Professional, 2000 or better is desirable.

C. Data previously submitted will not be considered; therefore, such data should not be relied upon nor incorporated in the technical proposal by reference. Failure to provide the information required to evaluate the proposal may result in rejection of that proposal without further consideration. General statements that the Offeror understands and can or will comply with all specifications, statements paraphrasing the specifications or parts thereof, and phrases such as "standard procedures will be employed" or "well known techniques will be used," will be considered insufficient.

D. The proposal shall be prepared in such a manner as to enable SAIC/NCI personnel and other affected parties to make a thorough and complete evaluation, and arrive at a sound determination as to whether or not the proposal will satisfy the requirement of SAIC/NCI. Offerors will organize their proposals to directly correspond with the evaluation factors as follows:

1. Experience, expertise and skills of the Offeror as demonstrated by submissions such as previous work experiences for similar projects.
2. Offeror's understanding of the statement of work objectives and all of its components.
3. Feasibility of the Offeror's proposed methodology/strategy in addressing the statement of work outputs and tasks.
4. Offeror's project plan outlining key activities such as clinical trial monitoring, training, and project management milestones and time frames.

ARTICLE L.5. VOLUME II -- MANAGEMENT PROPOSAL INSTRUCTIONS:

Describe the experience and qualifications, Include curriculum vitaes, of all personnel who will be assigned for direct work on this project.

1. Management: The Offeror should provide a description of its corporate capabilities, including facilities (including packaging and shipment), personnel, and experience. The Offeror shall provide a management plan describing management of subcontractors, if necessary.
2. Principal Investigator/Project Director: List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.
3. Other Investigators/Trainers/Monitors: List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.
4. Additional Personnel: List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis.
5. Subcontractors, Consultants: It is desirable to avoid consultants and sub-tier contractors. However, if unavoidable, evaluation criteria will be as stringent as of the Offeror. All terms and conditions of this contract must be included in any sub-tier contract for consulting or any other contract on this project. Verification of performance of flow-down of all terms and conditions of this Subcontract to subcontracts with others will be fully audited.

ARTICLE L.6. VOLUME III -- COST PROPOSAL INSTRUCTIONS:

A. An Offeror's cost proposal will be evaluated after determination of the technical proposal as acceptable.

B. Cost will be an unweighted evaluation factor to allow for concentration on the technical aspects of the proposals. This does not mean that cost is not considered in the evaluation process. The pricing is analyzed through cost and/or price analysis and an analysis of the proposal cost realism.

C. Offerors should include a payment address in the cost proposal volume of its offer if the payment address is different than the address shown on the offer.

D. Cost EstimateWorksheet, Attachment 1, will be provided electronically on request. (Contact Eugene B. Anderson, See Article G.1, Contract Representatives) The Cost Proposal data should not be limited to the Attachment 1 sample. Expansion and breakout of costs is necessary and expected. ALL items on the Cost Estimate Worksheet, Attachment 1, must be addressed in the Cost Proposal.

ARTICLE L.7. FAR 52.252-3 PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)

The following FAR provisions are applicable to evaluation of the offers and are incorporated by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a provision may be accessed electronically at http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) PROVISION:

FAR Provision No.	Title	Date
52.214-34	Submission of Offers in the English Language	Apr-1991
52.214-35	Submission of Offers in U.S. Currency	Apr-1991
52.215-1	Instructions to Offerors – Competitive Acquisition	Jan 2004
52.215-16	Facilities Capital Cost of Money	June 2003

ARTICLE L.8. RESTRICTIONS ON DISCLOSURE AND USE OF DATA

A. The proposal submitted in response to this RFP may contain data (trade secrets, business data, cost and pricing data, technical data, etc.) which the Offeror, including its prospective Subcontractor(s) does not want used or disclosed for any purpose other than for evaluation of the proposal.

B. Offerors who include in their proposals data that they do not want disclosed to the public for any purpose or used by the Government except for evaluation purposes shall:

1. Mark the title page with the following legend:

"This proposal includes data that shall not be disclosed (unless disclosure is required by the Freedom of Information Act, 5 USC 552, as amended) outside the Government and shall not be duplicated, used, or disclosed - in whole or in part - for any purposes other than to evaluate this proposal. If, however, a contract is awarded to this Offeror as a result of - or in connection with - the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restrictions. The data subject to this restriction are contained in sheets:"

[_____]
(insert numbers or other identification of sheets); and

2. Mark each sheet of data it wishes to restrict with the following legend:

"Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal."

PART VI – EVALUATION FACTORS FOR AWARD

SECTION M – EVALUATION FACTORS FOR AWARD

ARTICLE M.1. PROPOSAL EVALUATION PROCEDURE

A. Proposals will be evaluated for technical acceptability without consideration of cost. The evaluation will be based on the demonstrated capabilities of the Offeror in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. The evaluation factors to be used are listed in Article M.2. The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in selection in the event that two or more Offerors are determined to be essentially equal following the evaluation of all factors other than cost or price.

B. The cost/price information of all proposals found to be technically acceptable will be considered prior to establishment of a competitive range. A best-buy analysis will be performed taking into consideration: the results of the evaluation of technical proposals, cost/price analysis, and other factors. SAIC reserves the right to make award(s) consistent with the best overall interests of the NCI and to make a single award, multiple awards, or no award at all.

C. Negotiations may be conducted with all technically acceptable Offerors in the competitive range. However, SAIC reserves the right to award the contract without negotiations, as provided in FAR 15.306(a). Nevertheless, SAIC may communicate with an Offeror in order to clarify or verify information about its experience. Such communications will not constitute discussions within the meaning of FAR 15.306(d), and will not obligate SAIC to make a competitive range determination, conduct discussions, or solicit or entertain revised proposals, or final proposal revisions.

D. Negotiations will be closed simultaneously with all Offerors in the competitive range with time and date for submission of best and final offers, if applicable.

E. Unless all offers are rejected, award will normally be made to the technically acceptable Offeror(s) whose offer, conforming to the solicitation, has been determined responsible and will be the most advantageous in terms of technical/cost capability. However, SAIC reserves the right to reject any or all offers, to accept other than the lowest cost offer, and/or to waive informalities and minor irregularities in a proposal.

ARTICLE M.2. EVALUATION FACTORS

A. Technical Proposal – The evaluation of technical factors will be paramount in the selection. Technical factors will be weighted as identified below. Each technical factor listed below will be evaluated separately, as well as, in relationship to each other.

1. Experience, expertise and skills of the Offeror as demonstrated by submissions such as previous work experiences for similar projects and curriculum vitaes of assigned personnel. (25%)
   Bonus points may be given for experience in TB/Korea studies and similar projects.
2. Offeror's understanding of the statement of work objectives and all of its components. (25%)
3. Feasibility of the Offeror's proposed methodology/strategy in addressing the statement of work outputs and tasks. (25%).
   Bonus points may be given for experience in having certifiable translators and Korean speaking CRAs that are already part of the staff.
4. Offeror's project plan outlining key activities such as clinical trail monitoring, training, and project management milestones and timeframes. (25%)

B. Cost Proposal: The cost proposal will be considered separately from the technical evaluation. Cost proposals will be evaluated to determine if they are realistic and reasonable, to judge the Offeror's understanding of the technical performance requirements and the Offerors understanding of the requirement and the impact of the scale up of the project. While the cost proposal has no weighting, as the technical proposals approach substantial equality in evaluation, the cost factor will increase in importance as a discriminator between proposals and could become the determining factor in contract award.

ATTACHMENT 1

COST ESTIMATE WORKSHEET

PERIOD OF PERFORMANCE

FROM	THROUGH

Solicitation No.:

LABOR CATEGORY	HOURLY RATE	NUMBER OF HRS.	TOTAL SALARY	FRINGE %	FRINGE AMOUNT	OVERHEAD % (as applies to Labor + Fringe only)	OVERHEAD AMOUNT	TOTAL DIRECT LABOR
SUBTOTAL →								
CONSULTANT/SUBCONTRACT COSTS *(List names and services to be provided – attach agreement and pricing)*								
EQUIPMENT *(Provide description and basis of estimated price for each item; e.g., past invoices for similar items or vendor quotes)*								
MATERIALS/SUPPLIES *(Provide itemized list including basis for price, e.g., past invoices for similar items or vendor quotes)*								
TRAVEL *(List number of persons, days, destination, purpose of each trip and prices associated)*								
OTHER DIRECT COSTS *(Provide itemized list including basis for price, e.g., past invoices for similar items or vendor quotes)*								
OTHER INDIRECT COSTS OR OVERHEAD % *(NOT to include overhead previously applied to labor)* **General and Administrative @ ____% :** _____ **Fixed Fee @ ____ %:** _____ **Other:** _____								
TOTAL COSTS →								

ATTACHMENT 2
SAIC/NCI INSTRUCTIONS:
INVOICE REQUEST AND CONTRACT FINANCIAL REPORTING
FOR COST-REIMBURSEMENT CONTRACTS

General: The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice. **INVOICES THAT DO NOT PROVIDE THE BREAKDOWN OR DOCUMENTATION REQUESTED HEREIN MAY BE RETURNED WITHOUT PAYMENT.**

Format: Invoice Requests may be submitted on the payee's letter-head or self-designed form provided that it contains the information described herein.

Number of Copies: Original and l copy

Frequency: Invoice requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by pre-contract cost provisions.

Billing of Costs Incurred: If billed costs include: (l) costs of a prior billing period, but not previously billed; or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

Currency: All SAIC/NCI contracts are expressed in United States (U.S.) dollars. When payments are made in a currency other than U.S. dollars, billings on the contract shall be expressed, and payment shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the U.S. dollars authorized.

Costs Requiring Prior Approval: Costs requiring the contracting officer's approval, which are not set forth in an Advance Understanding in the contract shall be so identified and reference the Contracting Officer's Authorization. In addition, any cost set forth in an Advance Understanding shall be shown as a separate line item on the request.

Invoice Submission: Each invoice shall be identified as either:

(a) **Interim Invoice—** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice —** The completion invoice is submitted promptly upon completion of the work; but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date is later). The completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.

(c) **Final Invoice —** A final invoice may be required after the amounts owed have been settled between SAIC and the Contractor (e.g., resolution of all suspensions and audit exceptions).

INVOICE PREPARATION AND DOCUMENTATION REQUIREMENTS

The Contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice.

(a) **Designated Billing Office Name and Address —** Enter the designated billing office name and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice.

(b) **Invoice Number —** Insert the appropriate serial number of the invoice.

(c) **Date Invoice Prepared —** Insert the date the invoice is prepared.

(d) **Contract Number and Date —** Insert the contract number and the effective date of the contract.

(e) **Payee's Name and Address —** Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract —** Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) **Total Fixed-Fee —** Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.

(h) **Billing Period** C Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) **Amount Billed for Current Period —** Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the current period.

(j) **Cumulative Amount from Inception —** Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) **Direct Costs —** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(l) **Direct Labor —** Provide breakdown of each labor category, hours worked and hourly rate charged and amount billed. *(Time cards may be requested on a random basis.)*

(2) **Fringe Benefits —** Cite rate, amount and base to which it is applied and amount billed. If rate has changed since award, explain the rationale for the change.

(3) **Accountable Personal Property —** Include permanent research equipment and general purpose equipment having a unit acquisition cost of $5,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property (http://amb.nci.nih.gov/reference/amblinks.htm*). Show permanent research equipment separate from general purpose equipment. Prepare and attach form entitled: Report of Capitalized Nonexpendable Equipment included in this contract.

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.
- The Contracting Officer's approval letter and number, if the equipment is not covered by the Property Schedule.
- Be preceded by an asterisk (*) if the equipment is below the approval level. Further itemization of invoices shall only be required for items having specific limitations set forth in the contract.

(4) **Overhead —** Cite rate, amount and base to which it is applied and amount billed. If rate has changed since award, explain the rationale for the change.

(5) **Materials and Supplies —** Include equipment with unit costs of less than $5,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount. Attach invoices from vendors or a consolidated listing providing individually listed equipment/supplies and the amount paid.

(6) **Premium Pay —** List remuneration in excess of the basic hourly rate and attach the Contracting Officers approval letter.

(7) **Consultant Fee —** List fees paid to consultants. Identify consultant by name or category as set forth in the contract's Advance Understanding or in the Contracting Officer's approval letter, hours worked, rate charged and amount. (Attach consultant's invoice)

(8) **Travel —**Identify travelers, dates, destination , purpose of trip, and amount. Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel. (Attach travel expense report)

(9) **Subcontract Costs —** List Subcontractor(s) by name and amount billed. Describe services provided. (Attach Subcontractor invoices)

(10) **Other —** List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(l) **Cost of Money (COM) —** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) **Indirect Costs—Overhead or General and Administrative Costs (G&A)** Cite rate, amount and base to which it is applied and amount billed. If rate has changed since award, explain the rationale for the change.

(n) **Fixed-Fee Earned —** Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract. Any withholding amount must be shown separately.

(o) **Total Amounts Claimed —** Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments —** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal. (Provide explanation and rationale for adjustment)

(q) **Grand Totals**

SAMPLE INVOICE

(a) Billing Office Name and Address

Ms. Lori Brooks
NCI at Frederick
SAIC Frederick
P.O. Box B
Frederick, MD 21702-1201

(b) Invoice No. _____

(c) Date Invoice Prepared _____

(d) Contract No. and Effective Date _____

(f) Total Estimated Cost of Contract _____

(g) Total Fixed Fee _____

(e) Payee's Name and Address
ABC CORPORATION
100 Main Street
Anywhere, U.S.A. Zip Code

Attention: Name, Title, and Phone Number of
Official to Whom Payment is Being Sent

(h) This invoice represents reimbursable costs from May 1, 2002 through May 31, 2002

	(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception
(k) Direct Costs		
(1) Direct Labor		
Principle Investigator ($32.00 x 100 Hours = $3,200)		
Technical Assistant ($15.00 x 40 Hours = $600)		
Total Direct Labor	$ 3,800.00	$ 10,000.00
(2) Fringe Benefits (15% x $3,800)	570.00	1,500.00
(3) Overhead (47% x $3,800 DL + $570 FB = $4,370)	2,053.00	5,405.00
(4) Accountable Personal Property		
(Attach Form Entitled Report of Capitalized Nonexpendable Equipment)		
Permanent Research (see attached invoice from vendor)	3,000.00	3,000.00
General Purpose (see attached invoice from vendor)	2,000.00	2,000.00
(5) Materials and Supplies (see attached invoice from vendor)	2,000.00	4,000.00
(6) Premium Pay (see attached authorization from Contracting Officer)	-0-	-0-
(7) Consultant Fee - Dr. Jones (1 day @ $100 [COA #3])	100.00	500.00
(8) Travel (see attached traveler, destination, etc.) (Domestic)	200.00	1,000.00
(see attached traveler, destination, etc.) (Foreign)	200.00	1,000.00
(9) Subcontract for rental space (see attached invoice from vendor)	1,500.00	3,000.00
(10) Other (see attached invoice from vendor)	100.00	300.00
Total Direct Costs	**$ 15,623.00**	**$ 31,705.00**
(l) Cost of Money (Factor) of (Appropriate Base)	2,400.00	3,600.00
(m) Indirect Costs -		
_____% of Direct Labor or Other Base (Formula)	4,000.00	6,000.00
(n) Fixed-Fee Earned (Formula)	700.00	1,400.00
(o) **Total amount Claimed**	**$ 22,623.00**	**$ 42,705.00**
(p) **Adjustments**		
Outstanding Suspensions		**$ (1,700.00)**
(q) **Grand Totals**	**$ 22,723.00**	**$ 41,005.00**

"I certify that all payments requested are for appropriate purposes and in accordance with the contract."

(Name of Official) (Title)

FINANCIAL REPORTING INSTRUCTIONS:

These instructions are keyed to the Columns on the Financial Report Of Individual Project/Contract, NIH Form 2706 to be completed for contracts in excess of $500,000.

Column A—Expenditure Category – Enter the expenditure categories required by the contract.

Column B—Cumulative Percentage of Effort/Hrs.-Negotiated – Enter the percentage of effort or number of hours agreed to doing contract negotiations for each employee or labor category listed in Column A.

Column C—Cumulative Percentage of Effort/Hrs.-Actual – Enter the percentage of effort or number of hours worked by each employee or labor category listed in Column A.

Column D—Incurred Cost-Current – Enter the costs, which were incurred during the current period.

Column E—Incurred Cost-Cumulative – Enter the cumulative cost to date.

Column F—Cost at Completion – Enter data only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column G—Contract Amount – Enter the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column H—Variance (Over or Under) – Show the difference between the estimated costs at completion (Column F) and negotiated costs (Column G) when entries have been made in Column F. This column need not be filled in when Column F is blank. When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column F by Column G, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications: Any modification in the amount negotiated for an item since the preceding report should be listed in the appropriate cost category.

Expenditures Not Negotiated: An expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in, except for G. Column H will of course show a 100 percent variance and will be explained along with those identified under H above.

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT, NIH FORM 2706 *Note: Complete this Form in Accordance with Accompanying Instructions.*	Project Task:	Contract No.:	Date of Report:	0990-0134 0990-0131
	Reporting Period:	Contractor Name and Address:		

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost-- Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Funded Contract Amount	Variance (Over or Under) (I - H)
	Funded	Actual							
A	B	C	D	E	F	G	H	I	J

Note: Complete this Form in Accordance with Accompanying Instructions.	**Reporting Period:**	**Contractor Name and Address:**

Expenditure Category	**Percentage of Effort/Hours**		**Cumulative Incurred Cost at End of Prior Period**	**Incurred Cost-- Current Period**	**Cumulative Cost to Date (D + E)**	**Estimated Cost to Complete**	**Estimated Cost at Completion (F + G)**	**Funded Contract Amount**	**Variance (Over or Under) (I - H)**
	Funded	**Actual**							
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**

INSTRUCTIONS FOR PREPARATION OF REPORT OF CAPITALIZED NONEXPENDABLE EQUIPMENT

This report shall be submitted in an original by the contractor and included with the invoice under which reimbursement >$5,000 for the acquisition of authorized accountable personal property is requested. When utilizing this form for inventory reporting, two copies shall be forwarded to the Contract Administrator.

Item No.

1. Enter date prepared.

2. Enter Public Voucher (or invoice) Number.

3. Enter complete contract number.

4. Enter number of this report. (Reports will be numbered serially beginning with No. 1 for each contract.) Enter page number of pages.

5. Enter name and telephone number of contractor's representative responsible for report.

6. Indicate type of Report.

7. Enter name and address of contractor exactly as it appears on the contract.

8. Leave blank. For Contracting Agency use only.

9. Enter line item number. Each report shall begin with number "1".

10.-14 Identify fully the property being reported, including manufacturer, model, type, capacity, size and serial number. When this form is used for inventory reporting, include condition code in item 10 and indicate GFP or CAP in item 11.

15. Enter unit acquisition cost of the item. (List all taxes, discounts, shipping and installation costs as separate items immediately following each item being reported.)

16. This item shall be completed for inventory reporting. For Government owned property, enter the Government identification number (decal) affixed. For Contractor owned property, enter contractor's identification number affixed.

17. Enter authorization for acquisition e.g., contract schedule number, contracting officer's authorization letter number, etc.

18. Enter month and year property was received by contractor as reflected on receiving report.

19. Enter signature and title of person authorized to certify to the accuracy of report.

20. Leave blank. For contracting Agency use only.

REPORT OF CAPITALIZED NON-EXPENDABLE EQUIPMENT					1. Date	2. Public Voucher No.			
					3. Contract No.	4. Report No.	Page No. 1	No. of Pages 1	
5. Person Responsible Telephone:		6. Type of Report □ Acquisition - Govt. Titled □ Acquisition - Contractor Titled □ Annual Inventory □ Final Inventory			7. Name and Address of Contractor			8. SAIC Use Only	
9. Item No.	10. Description	11. GFP/CAP	12. Manufacturer	13. Model	14. Serial	15. Cost	16. Govt. ID	17. Acq. Aut.	18. Date
19. Authentication By Contractor=s Supervisory Accounting Official Signature: _____ Date:				20. Accepted by Authorized SAIC-Frederick Inc. Representative				Voucher No.	
Name (Typed)	Title			Signature & Title				Date	

ATTACHMENT 3

PART IV – SECTION K
Representations, Certifications, and Other Statements of Offerors (Negotiated).

1.	FAR 52.203-2	Certification of Independent Price Determination
2.	FAR 52.203-11	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (DEVIATION)
3.	FAR 52.204-3	Taxpayer Identification
4.	FAR 52.204-5	Women-Owned Business (Other Than Small Business)
5.	FAR 52.204-6	Data Universal Numbering System (DUNS) Number
6.	FAR 52.209-5	Certification Regarding Debarment, Suspension, Proposed Debarment and Other Responsibility Matters
7.	FAR 52.215-6	Place of Performance
8.	FAR 52.219-1	Small Business Program Representations
9.	FAR 52.219-19	Small Business Concern Representation for the Small Business Competitiveness Demonstration Program
10.	FAR 52.219-21	Small Business Size Representation for Targeted Industry Categories Under the Small Business Competitiveness Demonstration Program
11.	FAR 52.219-22	Small Disadvantaged Business Status
12.	FAR 52.222-18	Certification Regarding Knowledge of Child Labor for Listed End Products
13.	FAR 52.222-21	Certification of Nonsegregated Facilities
14.	FAR 52.222-22	Previous Contracts and Compliance Reports
15.	FAR 52.222-25	Affirmative Action Compliance
16.	FAR 52.222-38	Compliance with Veterans' Employment Reporting Requirements
17.	FAR 52.222-48	Exemption From Application of Service Contract Act Provisions
18.	FAR 52.223-4	Recovered Material Certification
19.	FAR 52.223-13	Certification of Toxic Chemical Release Reporting
20.	FAR 52.225-2	Buy American Act--Balance of Payments Program Certificate
21.	FAR 52.225-4	Buy American Act--North American Free Trade Agreement--Israeli Trade Act—Balance of Payments Program Certificate
22.	FAR 52.225-6	Trade Agreements Certificate
23.	FAR 52.226-2	Historically Black College or University and Minority Institution Representation
24.	FAR 52.227-6	Royalty Information
25.	FAR 52.230-1	Cost Accounting Standards Notices and Certification
26.	-----	Certification Regarding Environmental Tobacco Smoke
27.	-----	Certification of Institutional Policy on Conflict of Financial Interest
28.	FAR 15.406-2	Certificate of Current Cost or Pricing Data

To Be Completed by the Offeror: **(The Representations and Certifications must be executed by an individual authorized to bind the offeror.)** The offeror makes the following Representations and Certifications as part of its proposal **(check/complete all appropriate boxes or blanks on the following pages)**.

_____ _____
(Name of Offeror) **(RFP No.)**

_____ _____
(Signature of Authorized Individual) **(Date)**

_____
(Typed Name of Authorized Individual)

Note: The penalty for making false statements in offers is prescribed in 18 U.S.C 1001

1. **52.203-2 CERTIFICATE OF INDEPENDENT PRICE DETERMINATION (APRIL 1985)**

[NOTE: This provision is applicable when a firm-fixed price or fixed-price with economic price adjustment contract is contemplated.]

(a) The offeror certifies that -

The prices in this offer have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to (i) those prices, (ii) the intention to submit an offer, or (iii) the methods or factors used to calculate the prices offered;

(1) The prices in this offer have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before bid opening (in the case of a sealed bid solicitation) or contract award(in the case of a negotiated solicitation) unless otherwise required by law; and

(2) No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition.

(b) Each signature on the offer is considered to be a certification by the signatory that the signatory--

(1) Is the person in the offeror's organization responsible for determining the prices being offered in this bid or proposal, and that the signatory has not participated and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above; or

(2) Has been authorized in writing, to act as agent for the following principals in certifying that those principals have not participated, and will not participate any action contrary to subparagraphs (a)(1)through (a)(3) above

[insert full name of person(s) in the offeror's organization responsible for determining the prices offered in this bid or proposal, and the title of his or her position in the offeror's organization];

(ii) As an authorized agent, does certify that the principals named in subdivision (b)(2)(i) above have not participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above; and

(iii) As an agent, has not personally participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above.

(c) If the offeror deletes or modifies subparagraph (a)(2) above, the offeror must furnish with its offer a signed statement setting forth in detail the circumstances of the disclosure.

2. **52.203-11 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (DEVIATION)**

(a) The definitions and prohibitions contained in the clause, at FAR 52.203-12, Limitations on Payments to Influence Certain Federal Transactions, included in this solicitation, are hereby incorporated by reference in paragraph (b) of this certification.

(b) The offeror, by signing its offer, hereby certifies to the best of his or her knowledge and belief that on or after December 23, 1989 –

(1) No Federal appropriated funds have been paid or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with the awarding of a contract

resulting from this solicitation.

(2) If any funds other than Federal appropriated funds (including profit or fee received under a covered Federal transaction) have been paid, or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with this solicitation, the offeror shall complete and submit with its offer, OMB Standard Form-LLL, "Disclosure of Lobbying Activities", to the Contracting Officer, and

(3) He or she will include the language of this certification in all Subcontract awards at any tier and require that all recipients of Subcontract awards in excess of $100,000 shall certify and disclose accordingly.

(c) Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by section 1352, Title 31, United States Code. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure form to be filed or amended by this provision, shall be subject to a civil penalty of not less than $10,000, and not more than $100,000, for each such failure.

3. **52.204-3 TAXPAYER IDENTIFICATION (OCTOBER 1998)**

(a) Definitions.

Common parent, as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

Taxpayer Identification Number (TIN), as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number.

(b) All offerors must submit the information required in paragraphs (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the IRS. If the resulting contract is subject to the payment reporting requirements described in Federal Acquisition Regulation (FAR) 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

(c) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(d) Taxpayer Identification Number (TIN).
[ ] TIN:
[ ] TIN has been applied for.
[ ] TIN is not required because:
[ ] Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;
[ ] Offeror is an agency or instrumentality of a foreign government;
[ ] Offeror is an agency or instrumentality of the Federal Government.

(e) Type of organization.
[ ] Sole proprietorship;

[ ] Partnership;
[ ] Corporate entity (not tax-exempt);
[ ] Corporate entity (tax-exempt);
[ ] Government entity (Federal, State, or local);
[ ] Foreign government;
[ ] International organization per 26 CFR 1.6049-4;
[ ] Other

(f) Common parent.

[ ] Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.
[ ] Name and TIN of common parent:
Name_____
TIN_____

4. **52.204-5 WOMEN-OWNED BUSINESS (Other Than Small Business) (MAY 1999)**

(a) *Definition*. Women-owned business concern, as used in this provision, means a concern that is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

(b) *Representation*. *[Complete only if the offeror is a women-owned business concern and has not represented itself as a small business concern in paragraph (b)(1) of FAR 52.219-1, Small Business Program Representations, of this solicitation*.] The offeror represents that it **[ ]** is a women-owned business concern.

5. **52.204-6 DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER (JUNE 1999)**

(a) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" followed by the DUNS number that identifies the offeror's name and address exactly as stated in the offer. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services.

(b) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one. A DUNS number will be provided immediately by telephone at no charge to the offeror. For information on obtaining a DUNS number, if located within the United States, the offeror should call Dun and Bradstreet at 1-800-333-0505. The offeror should be prepared to provide the following information:

(1) Company name.
(2) Company address.
(3) Company telephone number.
(4) Line of business.
(5) Chief executive officer/key manager.
(6) Date the company was started.
(7) Number of people employed by the company.
(8) Company affiliation.

(c) Offerors located outside the United States may obtain the location and phone number of the local Dun and Bradstreet Information Services office from the Internet home page at http://www.customerservice@dnb.com. If an offeror is unable to locate a local service center, it may send an e-mail to Dun and Bradstreet at globalinfo@mail.dnb.com.

6. **52.209-5 CERTIFICATION REGARDING DEBARMENT, SUSPENSION, PROPOSED SUSPENSION, PROPOSED DEBARMENT AND OTHER RESPONSIBILITY MATTERS (DECEMBER 2001) (NOTE: Applies to contracts expected to exceed**

$100,000.)

(a) (1) The Offeror certifies, to the best of its knowledge and belief, that –

(i) The Offeror and/or any of its Principals --

(A) Are **[**], are not **[ ]** presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have **[**], have not **[**], within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state or local) contract or Subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(C) Are **[**], are not **[ ]** presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in subdivision (a)(1)(i)(B) of this provision.

(B) If the offeror has responded affirmatively, the offeror shall provide additional information if requested by the Contracting Officer; and

(ii) The Offeror has **[**], has not **[**], within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(3) "Principals" for the purposes of this certification, means officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (e.g., general manager, plant manager, head of a subsidiary, division, or business segment, and similar positions).

THIS CERTIFICATION CONCERNS A MATTER WITHIN THE JURISDICTION OF AN AGENCY OF THE UNITED STATES AND THE MAKING OF A FALSE, FICTITIOUS, OR FRAUDULENT CERTIFICATION MAY RENDER THE MAKER SUBJECT TO PROSECUTION UNDER SECTION 1001, TITLE 18, UNITED STATES CODE.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making an award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

7. **52.215-6 PLACE OF PERFORMANCE (OCTOBER 1997)**

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, **[ ]** intends, **[ ]** does not intend **(check applicable block)** to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of Performance (Street Address (City, State, County, Zip Code)	**Name and Address of Owner and Operator of the Plant) or Facility if Other than Offeror or Respondent**

8. **52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (MAY 2001)**

(Note: This provision applies to solicitations exceeding the micro-purchase threshold when the contract is to be performed in the United States, its territories or possessions, Puerto Rico, the Trust Territory of the Pacific Islands, or the District of Columbia.)

(a) (1) The North American Industry Classification System (NAICS) code for this acquisition is [INSERT NAICS CODE] .

(2) The small business size standard is [INSERT SIZE STANDARD] .

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b) **Representation**s.

(1) The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a small business concern.

(2) **(Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.)** The offeror represents, for general statistical purposes, that it **[ ]** is, **[ ]** is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) **(Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.)** The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a women-owned small business concern.

(4) **(Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.)** The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a veteran-owned small business concern.

(5) **(Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(4) of this provision.)** The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a service-disabled veteran-owned small business concern.

(c) **Definition**s. As used in this provision--

Service-disabled veteran-owned small business concern--

(1) Means a small business concern--

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock or which is owned by one or more service-disabled veterans; and

(ii) The Management and daily business operation of which are controlled by one or more service-disabled veterans or, in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

Small business concern, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

Women-owned small business concern, means a small business concern-

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

Veteran-owned small business concern means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S. C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

(d) **Notice.**

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small, HUBZone small, small disadvantaged, or women-owned small business concern in order to obtain a contract to be awarded under the preference programs established pursuant to section 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall—

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

ALTERNATE I (OCTOBER 2000). As prescribed in 19.307(a)(2), add the following paragraph (b)(6) to the basic provision:

(6) [Complete only if offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents, as part of its offer, that--

(i) It **[ ]** is, **[ ]** is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR part 126; and

(ii) It **[ ]** is, **[ ]** is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(4)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. [The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture:_____ .] Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

9. **52.219-19 SMALL BUSINESS CONCERN REPRESENTATION FOR THE SMALL BUSINESS COMPETITIVENESS DEMONSTRATION PROGRAM (OCTOBER 2000)**

(This representation must be completed if the acquisition is for one of the four designated industry groups of the SmallRepresentations and Certifications - Negotiated DECEMBER 27, 2001 8 Business Competitiveness Demonstration Program specified in FAR 19.1005(a)[includes Construction Contracts under NAICS codes that comprise Industry Subsectors 233, 234 and 235].)

(a) **Definition**

"Emerging small business" as used in this solicitation, means a small business concern whose size is no greater than 50 percent of the numerical size standard applicable to the North American Industry Classification System (NAICS) code assigned to a contracting opportunity.

(b) **(Complete only if offeror has represented itself under the provision at FAR 52.219-1 as a small business concern under the size standards of this solicitation.)**

The Offeror **[ ]** is, **[ ]** is not an emerging small business.

(c) **(Complete only if the Offeror is a small business or an emerging small business, indicating its size range.)**

Offeror's number of employees for the past twelve months **(check this column if size standard stated in solicitation is expressed in terms of number of employees)** or Offeror's average annual gross revenue for the last 3 fiscal years **(Check this column if size standard stated in solicitation is expressed in terms of annual receipts). (Check one of the following.)**

Number of Employees	**Average Annual Gross Revenues**
[ ] 50 or fewer	[ ] $1 million or less
[ ] 51 - 100	[ ] $1,000,001 - $2 million
[ ] 101 - 250	[ ] $2,000,001 - $3.5 million
[ ] 251 - 500	[ ] $3,500,001 - $5 million
[ ] 501 - 750	[ ] $5,000,001 - $10 million
[ ] 751 - 1,000	[ ] $10,000,001 - $17 million
[ ] Over 1,000	[ ] Over $17 million

10. **52.219-21 SMALL BUSINESS SIZE REPRESENTATION FOR TARGETED INDUSTRY CATEGORIES UNDER THE SMALL BUSINESS COMPETITIVENESS DEMONSTRATION PROGRAM (MAY 1999)**

(Complete only if the Offeror has represented itself under the provision 52.219-1 as a small business concern under the size standards of this solicitation.)

(NOTE: This representation must be completed if this solicitation covers one of the ten targeted industry categories under the Small Business Competitiveness Demonstration Program and if the offeror has certified itself under the clause at FAR 52.219-1 to be a small business concern under the size standards of this solicitation).

Offeror's number of employees for the past twelve months **(check this column if size standard stated in solicitation is expressed in terms of number of employees)** or Offeror's average annual gross revenue for the last three fiscal years **(check this column if size standard stated in solicitation is expressed in terms of annual receipts). (Check one of the following.)**

No. of Employees Average	**Annual Gross Revenues**
[ ] 50 or fewer	[ ] $1 million or less
[ ] 51 - 100	[ ] $1,000,001 - $2 million
[ ] 101 -250	[ ] $2,000,001 - $3.5 million
[ ] 251 - 500	[ ] $3,500,001 - $5 million
[ ] 501 - 750	[ ] $5,000,001 - $10 million
[ ] 751 - 1,000	[ ] $10,000,001 - $17 million
[ ] Over 1,000	[ ] Over $17 million

The ten targeted industries are as follows:

Product Service Code	SIC Code	Description
G004	8742	Counseling/Training/Social Rehabilitation Services
J099	7699	Maintenance, Repair and Rebuilding of Equipment (Office Machines, Text Processing Systems & Visible Record Equipment)
K099	7699	Modification of Equipment (misc.)
Q210	8099, 8742	General Health Care Services
R406	8742	Policy Review/Development Services
R497	7299	Personal Services
6505	2833, 2834 2835, 2836	Drugs and Biologics
7045	3572, 3695 5065	ADP Supplies
7110	5021	Office Furniture
7510	5112	Office Supplies

11. **52.219-22 SMALL DISADVANTAGED BUSINESS STATUS (OCTOBER 1999)**

(Note: This applies to competitive solicitations over $100,000 under the SIC Major Groups for which a price evaluation adjustment is applicable.)

(a) **General.** This provision is used to assess an offeror's small disadvantaged business status for the purpose of obtaining a benefit on this solicitation. Status as a small business and status as a small disadvantaged business for general statistical purposes is covered by the provision at FAR 52.219-1, Small Business Program Representation.

(b) **Representations.**

(1) **General.** The offeror represents, as part of its offer, that it is a small business under the size standard applicable to this acquisition; and either--

[ ] (i) It has received certification by the Small Business Administration as a small disadvantaged business concern consistent with 13 CFR 124, Subpart B; and

(A) No material change in disadvantaged ownership and control has occurred since its certification;

(B) Where the concern is owned by one or more disadvantaged individuals, the net worth of each individual upon whom the certification is based does not exceed $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(C) It is identified, on the date of its representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration (PRO-Net); or

[ ] (ii) It has submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantaged business concern in accordance with 13 CFR 124, Subpart B, and a decision on that application is pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

(2) **[ ] For Joint Ventures**. The offeror represents, as part of its offer, that it is a joint venture that complies with the requirements at 13 CFR 124.1002(f) and that the representation in paragraph (b)(1) of this provision is accurate for the small disadvantaged business concern that is participating in the joint venture. *[The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint venture: _____.]*

(c) **Penalties and Remedie**s. Anyone who misrepresents any aspects of the disadvantaged status of a concern for the purposes of securing a contract or Subcontract shall:

(1) Be punished by imposition of a fine, imprisonment, or both;
(2) Be subject to administrative remedies, including suspension and debarment; and
(3) Be ineligible for participation in programs conducted under the authority of the Small Business Act.

Alternate I (OCTOBER 1998)

(Note: Applies when price evaluation adjustment for small disadvantaged business concerns is authorized on a regional basis. Designated regions by Major SIC Category can be found at http://www.arnet.gov/References/sdbadjustments.htm. Currently, this includes SIC Major Industry Groups 15, 16, 17 which are all construction related groups.)

As prescribed in 19.306(b), add the following paragraph (b)(3) to the basic provision:

(3) Address. The offeror represents that its address_____is, _____is not in a region for which a small disadvantaged business procurement mechanism is authorized and its address has not changed since its certification as a small disadvantaged business concern or submission of its application for certification. The list of authorized small disadvantaged business procurement mechanisms and regions is posted at http://www.arnet.gov/References/sdbadjustments.htm The offeror shall use the list in effect on the date of this solicitation. "Address," as used in this provision, means the address of the offeror as listed on the Small Business Administration's register of small disadvantaged business concerns or the address on the completed application that the concern has submitted to the Small Business Administration or a Private Certifier in accordance with 13 CFR part 124, subpart B. For joint ventures, "address" refers to the address of the small disadvantaged business concern that is participating in the joint venture.

12. **52.222-18 CERTIFICATION REGARDING KNOWLEDGE OF CHILD LABOR FOR LISTED END PRODUCTS (MAY 2001)**

(Applies to all contracts for supplies over $2,500. See FAR 22.1503 for more information)

a. *Definition*.

Forced or indentured child labor means all work or service--

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

b. *Listed end products.* The following end product(s) being acquired under this solicitation is (are) included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, identified by their country of origin. There is a reasonable basis to believe that listed end products from the listed countries of origin may have been mined, produced, or manufactured by forced or indentured child labor.

Listed End Product

_____
_____

Listed Countries of Origin

_____
_____

c. *Certification*. The Government will not make award to an offeror unless the offeror, by checking the appropriate block, certifies to either paragraph (c)(1) or paragraph (c)(2) of this provision.

[ ] (1) The offeror will not supply any end product listed in paragraph (b) of this provision that was mined, produced, or manufactured in a corresponding country as listed for that end product.

[ ] (2) The offeror may supply an end product listed in paragraph (b) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture such end product. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

13. **52.222-21 CERTIFICATION OF NONSEGREGATED FACILITIES (FEBRUARY 1999)**

(a) *Segregated facilities*, as used in this clause, means any waiting rooms, work areas, rest rooms and wash rooms, restaurants and other eating areas, time clocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees, that are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, sex, or national origin because of written or oral policies or employee custom. The term does not include separate or single-user rest rooms or necessary dressing or sleeping areas provided to assure privacy between the sexes.

(b) The Contractor agrees that it does not and will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not and will not permit its

employees to perform their services at any location under its control where segregated facilities are maintained. The Contractor agrees that a breach of this clause is a violation of the Equal Opportunity clause in this contract.

(c) The Contractor shall include this clause in every Subcontract and purchase order that is subject to the Equal Opportunity clause of this contract.

14. **52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (FEBRUARY 1999)**

The offeror represents that –

(a) It **[ ]** has, **[ ]** has not participated in a previous contract or Subcontract subject to the Equal Opportunity clause of this solicitation;

(b) It **[ ]** has, **[ ]** has not, filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed Subcontractors, will be obtained before Subcontract awards.

15. **52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APRIL 1984)**

The offeror represents that (a) it **[ ]** has developed and has on file, **[ ]** has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or (b) it **[ ]** has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

16. **52.222-38 COMPLIANCE WITH VETERANS' EMPLOYMENT REPORTING REQUIREMENTS (DECEMBER 2001)**

By submission of its offer, the offeror represents that, if it is subject to the reporting requirements of 38 U.S.C. 4212(d) (i.e., if it has any contract containing Federal Acquisition Regulation clause 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans), it has submitted the most recent VETS-100 Report required by that clause.

17. **52.222-48 EXEMPTION FROM APPLICATION OF SERVICE CONTRACT ACT PROVISIONS FOR CONTRACTS FOR MAINTENANCE, CALIBRATION, AND/OR REPAIR OF CERTAIN INFORMATION TECHNOLOGY, SCIENTIFIC AND MEDICAL AND/OR OFFICE AND BUSINESS EQUIPMENT—CONTRACTOR CERTIFICATION (AUGUST 1996)**

(NOTE: This clause is applicable to all solicitations and resultant contracts calling for maintenance, calibration, and/or repair of information technology, scientific and medical, and office and business equipment if the contracting officer determines that the resultant contract may be exempt from Service Contract Act coverage).

(a) The following certification shall be checked:

CERTIFICATION

The offeror certifies **[**], does not certify **[ ]** that: (1) The items of equipment to be serviced under this contract are commercial items which are used regularly for other than Government purposes, and are sold or traded by the Contractor in substantial quantities to the general public in the course of normal business operations; (2) The contract services are furnished at prices which are, or are based on, established catalog or market prices for the maintenance, calibration, and/or repair of certain information technology, scientific and medical, and/or office and business equipment. An "established catalog price" is a

price (including discountprice) recorded in a catalog, price list schedule, or other verifiable and established record that is regularly maintained by the manufacturer or the Contractor and is either published or otherwise available for inspection by customers. An "established market price" is a currentprice, established in the usual course of ordinary and usual trade between buyers and sellersfree to bargain, which can be substantiated by data from sources independent of the manufacturer or Contractor; and (3) The Contractor utilizes the same compensation (wage and fringe benefits) plan for all service employees performing work under the contract as the Contractor uses for equivalent employees servicing the same equipment of commercial customers.

(b) If a negative certification is made and a Service Contract Act wage determination is not attached to the solicitation, the Contractor shall notify the Contracting Officer as soon as possible.

(c) Failure to execute the certification in paragraph (a) of this clause or to contact the Contracting Officer as required in paragraph (b) of this clause may render the bid or offer non-responsive.

18. **52.223-4 RECOVERED MATERIAL CERTIFICATION (OCTOBER 1997)**

(This certification is applicable in solicitations that are for, or specify the use, of recovered materials.)

As required by the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6962(c)(3)(A)(i)), the offeror certifies, by signing this offer, that the percentage of recovered materials to be used in the performance of the contract will be at least the amount required by the applicable contract specifications.

19. **52.223-13 CERTIFICATION OF TOXIC CHEMICAL RELEASE REPORTING (OCTOBER 2000)**

NOTE: This certification is applicable for all solicitations for competitive contracts expected to exceed $100,000 (including all options) and competitive 8(a) contracts. It is not applicable to acquisitions of commercial items, or to contracts where the contractor's facilities are located outside the United States (the "United States" includes any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, the Northern Mariana Islands, and any other territory or possession over which the United States has jurisdiction)

(a) Submission of this certification is a prerequisite for making or entering into this contract imposed by Executive Order 12969, August 8, 1995.

(b) By signing this offer, the offeror certifies that–

(1) As the owner or operator of facilities that will be used in the performance of this contract that are subject to the filing and reporting requirements described in section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11023) and section 6607 of the Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13106), the offeror will file and continue to file for such facilities for the life of the contract the Toxic Chemical Release Inventory Form (Form R) as described in sections 313(a) and (g) of EPCRA and section 6607 of PPA; or

(2) None of its owned or operated facilities to be used in the performance of this contract is subject to the Form R filing and reporting requirements because each such facility is exempt for at least one of the following reasons: (Check each block that is applicable.)

[ ] (i) The facility does not manufacture, process, or otherwise use any toxic chemicals listed under section 313(c) of EPCRA, 42 U.S.C. 11023(c);

[ ] (ii) The facility does not have 10 or more full-time employees as specified in section 313(b)(1)(A) of EPCRA, 42 U.S.C. 11023(b)(1)(A);

[ ] (iii) The facility does not meet the reporting thresholds of toxic chemicals established under section 313(f) of EPCRA, 42 U.S.C. 11023(f) (including the alternate thresholds at 40 CFR 372.27, provided an appropriate certification form has been filed with EPA);

[ ] (iv) The facility does not fall within Standard Industrial Classification Code (SIC) major groups 20 through 39 or their corresponding North American Industry Classification System (NAICS) sectors 31 through 33; or

[ ] (v) The facility is not located within any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, the Northern Mariana Islands, or any other territory or possession over which the United States has jurisdiction.

20. **52.225-2 <u>BUY AMERICAN ACT--BALANCE OF PAYMENTS PROGRAM CERTIFICATE (FEBRUARY 2000)</u>**

[Note: This provision is applicable for all requirements EXCEPT for 1) foreign contracts or 2) when one of the following two provisions (52.225-4, Buy American Act--North American Free Trade Agreement--Israeli Trade Act--Balance of Payments Program Certificate, or 52.225-6, Trade Agreements Certificate) apply.

(a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a domestic end product as defined in the clause of this solicitation entitled "Buy American Act--Balance of Payments Program--Supplies" and that the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

(b) Foreign End Products:

Line Item No.:_____
Country of Origin:_____
(List as necessary)

(c) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition Regulation.

21. **52.225-4 <u>BUY AMERICAN ACT NORTH AMERICAN FREE TRADE AGREEMENT—ISRAELI TRADE ACT-- BALANCE OF PAYMENTS PROGRAM CERTIFICATE (FEBRUARY 2000)</u>**

[Note: This provision is applicable for requirements with a value exceeding $25,000 but less than $186,000 EXCEPT for 1) foreign acquisitions or 2) acquisitions that are exempt from NAFTA and the Israeli Trade Act. (See FAR 25.401).]

(a) The offeror certifies that each end product, except those listed in paragraph (b) or (c) of this

provision, is a domestic end product (as defined in the clause of this solicitation entitled, "Buy American Act--North American Free Trade Agreement--Israeli Trade Act--Balance of Payments Program") and that the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States.

(b) The offeror certifies that the following supplies are NAFTA country end products or Israeli end products as defined in the clause of this solicitation entitled, "Buy American Act—North American Free Trade Agreement--Israeli Trade Act--Balance of Payments Program":

NAFTA Country or Israeli End Products:
Line Item No.:_____
Country of Origin:_____
(List as necessary)

(c) The offeror shall list those supplies that are foreign end products (other than those listed in paragraph (b) of this provision) as defined in the clause of this solicitation entitled, "Buy American Act--North American Free Trade Agreement--Israeli Trade Act--Balance of Payments Program." The offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

Other Foreign End Products
Line Item No.:_____
Country of Origin:_____
(List as necessary)

(d) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition Regulation.

ALTERNATE I (FEBRUARY 2000) As prescribed in 25.1101(b)(2)(ii), substitute the following paragraph (b) for paragraph (b) of the basic provision:

[Note: Applies when the acquisition value exceeds $25,000 but is less than $50,000.]

(b) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled "Buy American Act--North American Free Trade Agreement--Israeli Trade Act--Balance of Payments Program":

Canadian End Products:
Line Item No.:_____
(List as necessary)

ALTERNATE II (FEBRUARY 2000) As prescribed in 25.1101(b)(2)(iii), substitute the following paragraph (b) for paragraph (b) of the basic provision:

[Note: Applies when the acquisition value is $50,000 or more, but is less than $53,150.]

(b) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled "Buy American Act--North American Free Trade Agreement--Israeli Trade Act--Balance of Payments Program":

Canadian or Israeli End Products
Line Item No.:_____
Country of Origin:_____
(List as necessary)

22. **52.225-6 TRADE AGREEMENTS CERTIFICATE - (FEBRUARY 2000)**

[Note: This provision is applicable for acquisitions valued at $186,000 or more, if the Trade Agreement Act applies. (See FAR 25.401 and 25.403).]

(a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a U.S.-made, designated country, Caribbean Basin country, or NAFTA country end product, as defined in the clause of this solicitation entitled "Trade Agreements."

(b) The offeror shall list as other end products those supplies that are not U.S.-made, designated country, Caribbean Basin country, or NAFTA country end products.

Other End Products
Line Item No.:_____
Country of Origin:_____
(List as necessary)

(c) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition Regulation. For line items subject to the Trade Agreements Act, the Government will evaluate offers of U.S.-made, designated country, Caribbean Basin country, or NAFTA country end products without regard to the restrictions of the Buy American Act or the Balance of Payments Program. The Government will consider for award only offers of U.S.-made, designated country, Caribbean Basin country, or NAFTA country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of this solicitation.

23. **52.226-2 HISTORICALLY BLACK COLLEGE OR UNIVERSITY AND MINORITY INSTITUTION REPRESENTATION - (MAY 2001)**

(a) Definitions. As used in this provision--

Historically Black College or University means an institution determined by the Secretary of Education to meet the requirements of 34 CFR 608.2. For the Department of Defense, the National Aeronautics and Space Administration, and the Coast Guard, the term also includes any nonprofit research institution that was an integral part of such a college or university before November 14, 1986.

Minority Institution means an institution of higher education meeting the requirements of Section 1046(3) of the Higher Education Act of 1965 (20 U.S.C. 1067k, including a Hispanic-serving institution of higher education, as defined in Section 316(b)(1) of the Act (20 U.S.C. 1101a.)).

(b) *Representatio*n. The offeror represents that it--
[ ] is **[ ]** is not a Historically Black College or University;
[ ] is **[ ]** is not a Minority Institution.

24. **52.227-6 ROYALTY INFORMATION - (APRIL 1984)**

(a) **Cost or charges for royalties.** When the response to this solicitation contains costs or charges for royalties totaling more than $250, the following information shall be included in the response relating to each separate item of royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers, patent application serial numbers or other basis on which the royalty is payable.
(4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable.
(5) Percentage or dollar rate of royalty per unit.

(6) Unit price of contract item.
(7) Number of units.
(8) Total dollar amount of royalties.

(b) **Copies of current license**s. In addition, if specifically requested by the Contracting Officer before execution of the contract, the offeror shall furnish a copy of the current license agreement and an identification of applicable claims of specific patents.

(NOTE: Alternate I, below, is applicable for communication services and facilities by a common carrier.)

ALTERNATE I (APRIL 1984), 52.227-6 ROYALTY INFORMATION (APRIL 1984)

Substitute the following for the introductory portion of paragraph (a) of the basic clause: When the response to this solicitation covers charges for special construction or special assembly that contain costs or charges for royalties totaling more than $250, the following information shall be included in the response relating to each separate item of royalty or license fee:

25. **52.230-1 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (JUNE 2000)**

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS-coverage pursuant to 48 CFR 9903.201-2(C)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement -- Cost Accounting Practices and Certification

(a) Any contract in excess of $500,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contracts which are exempt as specified in 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

CAUTION: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

[ ] (1) Certificate of Concurrent Submission of Disclosure Statement.

The offeror hereby certifies that, as part of the offer, copies of the Disclosure Statement

have been submitted as follows:

(i) original and one copy to the cognizant Administrative Contracting Officer (ACO), or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable, and;

(ii) one copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official and/or from the looseleaf version of the Federal Acquisition Regulation).

Date of Disclosure Statement:_____
Name and Address of Cognizant ACO or Federal Official Where Filed: _____
_____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

[ ] (2) Certificate of Previously Submitted Disclosure Statement.

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement:_____
Name and Address of Cognizant ACO or Federal Official Where Filed: _____
_____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

[ ] (3) Certificate of Monetary Exemption.

The offeror hereby certifies that the offeror together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and Subcontracts subject to CAS totaling more than $50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

[ ] (4) Certificate of Interim Exemption.

The offeror hereby certifies that:

(i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted, and

(ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

CAUTION: Offerors currently required to disclose because they were awarded a

CAS-covered prime contract or Subcontract of $50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

[ ] (5) Certificate of Disclosure Statement Due Date by Educational Institution. (ALTERNATE I - APRIL 1996) If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903-202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that ***(check one and complete)***:

[ ] (i) A Disclosure Statement filing Due Date of _____has been established with the cognizant Federal agency.

[ ] (ii) The Disclosure Statement will be submitted within the 6-month period ending _____ months after receipt of this award.

Name and Address of Cognizant ACO or Federal Official Where Disclosure Statement is to be Filed:_____
_____

II. Cost Accounting Standards -- Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

[ ] The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than $50 million in awards of CAS-covered prime contracts and Subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

CAUTION: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of $50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or Subcontract of $50 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards Clause, require a change in established cost accounting practices affecting existing contracts and Subcontracts.

[ ] YES **[ ]** NO

26. **CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE (DECEMBER 1994)**

(Note: This certification applies only to those contract which contain provisions for children's services. The offeror's signature on the face page of these Representations and Certifications constitutes certification by the submitting organization of its compliance with the Act.)

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By signing this certification, the offeror/contractor (for acquisitions) or applicant/grantee (for grants) certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

27. **CERTIFICATION OF INSTITUTIONAL POLICY ON CONFLICT OF FINANCIAL INTEREST (OCTOBER 1995)**

(Note: This certification is applicable to Research and Development (R&D) Contracts. However, this certification does not apply to SBIR-Phase I contractors.)

By submission of its offer, the offeror certifies that:

(1) A written and enforced administrative process to identify and manage, reduce or eliminate conflicting financial interest with respect to all research projects for which funding is sought from the NIH is **[**], is not **[ ]** currently in effect.

(2) Should a process not be in effect at the time of the submission of its offer, the offeror certifies that it will, no later than 30 days subsequent to submission of its offer or prior to award, whichever is earlier, notify the Contracting Officer of the establishment of a written and enforced financial conflict of interest policy.